UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

APPLIED MEDICAL RESOURCES CORPORATION, Plaintiff, v. TYCO HEALTHCARE GROUP LP d/b/a COVIDIEN, Defendant.	SACV 11-01406 JVS (ANx) Consolidated with SACV 12-00024 JVS (ANx) and SACV 14-00087 JVS (ANx) COURT'S FINDINGS OF FACT AND CONCLUSIONS OF LAW

This matter was tried to the Court on March 11-13 and April 4, 2014. Consistent with the Court's practice in bench trials (see Docket No. 275), direct testimony was received by way of declaration. The declarant then stood for cross-examination and, in most cases, redirect and recross.

The operative pleadings are the Complaint of Gaya Limited, Covidien LP, and Covidien Sales's (collectively, "Gaya") seeking a determination with regard to inventorship concerning certain patents held by Applied Medical Resources Corporation ("Applied")[1] and Applied's Answer.[2]

Pursuant to Rule 52(a) of the Federal Rules of Civil Procedure, the Court now enters its findings of fact and conclusions of law.

PROCEDURAL POSTURE OF THE CASE

As set forth in the Court's Pretrial Conference Order (Docket No. 293), the Court conducted a trial on the following issue: whether Gaya has shown by clear and convincing evidence that inventorship should be corrected on U.S. Patent Nos. 7,473,221 (the "'221 patent"); 7,481,765 (the "'765 patent"); 8,105,234 (the "'234 patent"); 8,016,755 (the "'755 patent"); and 8,496,581 (the "'581 patent") (collectively, "the Applied Patents"), including whether and which of Martin

1 See SACV 13-24 JVS (ANx), Docket No. 1 ("Inventorship Action"). The Inventorhsip Action was consolidated with other actions between the principal parties.

2 Id., Docket No. 22.

Caldwell ("Caldwell"), Donal Bermingham ("Bermingham"), Damien Rosney ("Rosney") and Christy Cummins ("Cummins") should be added as inventors and whether and which of the named Applied inventors have been improperly named.

The parties each reserved their right to have the Court determine whether this case should be deemed an exceptional case under 35 U.S.C. § 285 and whether the parties should be awarded their attorney fees.

FINDINGS OF FACT

A. Background.

1. Applied Medical.

1. Applied is a California corporation specializing in the development, manufacture, and marketing of various medical devices, including access devices. (Hilal, ¶ 1.)[3]

2. Applied developed "universal seal" technology for use with trocars in laparoscopic surgery. (Id., ¶ 5.) A "universal seal" refers to the ability of a single trocar to seal with different instrument sizes without requiring an adapter. (Id.)

3 The parties' trial declarations are cited by the last name of the witness, here Nabil Hilal.

3. Applied learned about the nascent hand-assisted laparoscopic surgery ("HALS") technology in 1995, when an Applied employee saw a presentation on HALS at a medical convention. (Id., ¶ 8.) Because the technology was so new, most surgeons had not yet accepted it and Applied did not pursue a product at that time. (Id.)

2. Gaya.

4. Gaya is an Irish patent holding company formed in 1994. (Caldwell, ¶ 2.) Medtech, a sister company of Gaya, was an entity licensed by Gaya to research, develop, and manufacture patented Gaya inventions. (Id., ¶ 3.) For ease of reference, the Court will refer the to two companies simply as "Gaya."

5. In 1997, Gaya developed a HALS device that it called the "Intromit." (Caldwell, ¶ 6.) The Intromit included an inner plastic sleeve and an outer plastic sleeve that were joined at their upper edges to form an inflatable chamber. (Hilal, ¶ 11; see also Ex. 933 (product); Ex. 934 (photos of product); Ex. 375 (Instructions for Use).) A passageway through the inner sleeve allowed a surgeon's hand to pass through. (Hilal, ¶ 11.) A "taut valve" at the lower end of the passageway acted as a zero seal, preventing air from escaping the abdomen when nothing passed through the device. (Id., ¶¶ 11-13.) A "feathered valve" or an elastic band at an end of the passageway sealed around the surgeon's arm when it was inserted through the passageway, opening the taut valve. (Id., ¶ 11.) The device attached

directly to the patient's abdomen with an adhesive flange. (Id., ¶ 12.)

6. From 1994 to 2001, Gaya focused its research and development efforts on HALS devices. (Caldwell, ¶ 4.) Gaya was a pioneer in the creation of HALS devices. (Caldwell, ¶ 4.)

7. Gaya's R&D team engaged in extensive research and development of next generation HALS devices. (Cummins, ¶ 5.) The R&D team included Caldwell, Rosney, Bermingham, and Cummins. (Id., ¶ 16.)

8. Caldwell joined Gaya in June 1995. (Caldwell, ¶¶ 1-2.) Caldwell's early work at Gaya involved the Intromit, Gaya's first-generation HALS access device. (Id., ¶ 2.) In view of the perceived shortcomings of the Intromit, in early 1998 Caldwell initiated a program to develop a next-generation HALS device. (Id., ¶ 14.)

9. Bermingham was a process and manufacturing engineer for Gaya from approximately mid-1997 through early 2001. (Bermingham, ¶ 1.) Bermingham's primary responsibilities at Gaya were developing and improving the manufacturing process for the Intromit and also for developing next-generation HALS devices. (Id.)

10. Rosney was a production manager for Gaya from approximately 1996 to

2001. (Rosney, ¶ 2.) In that capacity, Rosney had overall responsibility for manufacturing the Intromit and was also involved in research and development of next generation HALS devices. (Id., ¶¶ 4-5.)

11. Cummins was employed as a research and development consultant for Gaya from October 1998 to September 1999. (Cummins, ¶ 1.) Cummins' primary responsibilities were to make improvements to the Intromit, and to design and develop the next generation of Gaya HALS devices. (Id., ¶ 15.)

3. Initial Relationship Between Applied And Gaya.

12. In 1999, Gaya approached Applied to discuss licensing the Intromit. (Hilal, ¶ 15.) The parties entered into a Secrecy Agreement in September 1999 to facilitate further discussions regarding rights to the Intromit. (Id., ¶ 18; Ex. 735 (Secrecy Agreement).) In February 2000, Applied and Gaya entered into a Patent License and Option Agreement under which Applied received a license from Gaya to sell the Intromit product. (Ex. 737 (Patent License and Option Agreement).) Applied also obtained an option to certain patents owned by Encoret (another patent holding company related to Gaya) ("Encoret Option"). (Id.) Gaya had represented that Encoret patents could be asserted to restrict HALS activity by competitors, such as Dexterity and Smith & Nephew, if Gaya (through Encoret) prevailed in a patent interference proceeding with Dexterity. (See Hilal, ¶¶ 26-27, 41.) Gaya's claims in the interference proceeding were rejected. (Id., ¶ 41.) As a

result, Applied never considered exercising the Encoret Option. (Id., ¶¶ 39-41.)

13. In connection with its negotiations with Gaya, Applied gathered additional information regarding existing HALS technologies on the market and reviewed issued patents for HALS devices. (Brustad, ¶ 12.) This included reviewing Gaya's patents on the Intromit and obtaining copies of more than sixty issued patents related to HALS technology. (Id., ¶ 15.)

14. Applied also discussed HALS technology with surgeons and other companies operating in the field. (See id., ¶ 9.) For example, on December 3, 1999, a Urologist named Dr. Clayman met with Applied engineers to discuss product needs and future development concepts for HALS devices. (Id.) Dr. Clayman brought with him a liquid-filled toroid bladder that he suggested could act as a possible sealing concept for trocar or HALS applications. (Id.) Following the visit, Applied evaluated possible concepts using an inverting toroid seal. (Id., ¶ 10.) On December 30, 1999, Applied prepared an invention disclosure – naming Dr. Clayman as one of the inventors – that used this concept for both HALS and trocar seals. (See Ex. 988.) However, Applied ultimately determined that the concept did not work, and Applied did not pursue it further. (Brustad, ¶ 11.)

15. In January 2000, Applied employees Nabil Hilal ("Hilal) and John Brustad ("Brustad") visited the facilities of Dexterity, a company that was producing and selling a HALS device. (Id., ¶ 28; Hilal, ¶ 34.) At the time,

Dexterity was the leading company with a HALS device in the U.S. market. (Hilal, ¶ 30.) Hilal and Brustad discussed HALS devices and the HALS market with individuals from Dexterity. (Id., ¶ 34.)

4. Applied Visits Gaya In Ireland.

16. Applied began selling the Intromit in March 2000. (Hilal, ¶ 42.) At the time, Gaya was manufacturing the Intromit in Ireland. (Johnson, ¶ 10.) Applied's preferred option was to transfer the manufacturing and assembly of the Intromit to Applied's facilities in Orange County, California in order to respond more quickly to the evolving needs of surgeons. (Id.) Applied had not ruled out the possibility of setting up a permanent manufacturing facility in Ireland, however. (Id., ¶ 12.)

17. Two Applied engineers, Gary Johnson ("Johnson") and Scott Taylor ("Taylor"), visited Gaya's facilities in Ireland on March 23 and 24, 2000 to learn about the Intromit manufacturing process and to explore the options for a permanent manufacturing site for the Intromit. (Johnson, ¶¶ 12-14; Taylor, ¶¶ 6-7; see also Ex. 806 (Agenda).) They were hosted by Gaya employees Bermingham and Rosney. (Johnson, ¶ 15; Taylor, ¶ 10.) As discussed more fully below, no proprietary Gaya information was disclosed, and the March 23-24 meeting does not support any claim of co-inventorship.

18. On the morning of the first day of the visit, Johnson and Taylor

reviewed Intromit design and manufacturing documentation. (Johnson, ¶ 17; Taylor, ¶¶ 12-13.) That afternoon, they inspected the actual manufacturing equipment. (Johnson, ¶ 19; Taylor, ¶ 15.)

19. On the second day of the visit, Johnson and Taylor spent the morning reviewing product labeling and shipping logistics with Gaya personnel. (Johnson, ¶ 21; Taylor, ¶ 17.) They also discussed shipping the manufacturing equipment to Applied's facilities. (Johnson, ¶¶ 23-24; Taylor, ¶¶ 18-19.)

20. Also that morning, Caldwell showed Taylor and Johnson a prototype of a trocar concept called the "Introcar." (Johnson, ¶ 23; Taylor, ¶ 18.) Caldwell wished to discuss the Introcar with Applied so that Applied could assist Gaya with its development. (See Ex. 809 at CV11-1406AM0067283.) Prior to reviewing the Introcar, at Gaya's request, Taylor and Johnson signed a confidentiality agreement. (See Ex. 809.) Johnson called Hilal before signing to discuss whether they should do so. (Johnson, ¶ 23; Hilal, ¶ 48.)

21. In the afternoon, Johnson and Taylor spent additional time inspecting and recording aspects of the Intromit manufacturing equipment. (Johnson, ¶ 28; Taylor, ¶ 21.) They sought a full understanding of the manufacturing process in order to be able to transfer the manufacturing to Applied's facilities in California. (Taylor, ¶ 21.) They also personally went through the steps of manufacturing an Intromit. (Id.) Taylor took photos of Johnson and two Gaya employees

performing steps of the manufacturing process. (Ex. 811; see also Johnson, ¶ 28; Taylor, ¶ 21.)

22. Johnson was the Vice President of Operations and Facilities and Manager of Product Development for General Surgery at the time. (Johnson, ¶ 4.) Johnson was focused on the possible transitioning of the manufacturing of the Intromit from Ireland to the United States, and also went on the trip to review the potential for creating a second distribution center for Applied in Ireland. (Day 3 Tr., pp. 110:16-111:17.) Although he had some involvement with the Intromit, most of Johnson's time from February 2000 until June 2001 was spent managing the relocation of Applied's facilities from Laguna Hills to Rancho Santa Margarita. (Johnson, ¶ 5.)

5. Applied Improves The Intromit.

23. In April 2000, Applied began to receive reports of problems with the Intromit. (Hilal, ¶ 50.) Applied withdrew the Intromit from a planned full market release. (Taylor, ¶ 28.) Applied directed a group of engineers in its General Surgery Division to resolve the technical limitations with the Intromit and to attempt to solve the clinical limitations of the device. (Hilal, ¶¶ 58-59.) This group was led by Taylor. (Taylor, ¶¶ 28-42.) He coordinated with Gaya to address the limitations of the Intromit. (Id.) The group also included Norman Morales ("Morales") and Hank Kahle ("Kahle") of Applied. (Id, ¶ 29.)

24. Taylor's team engaged in a significant amount of work to resolve the problems with the Intromit. (Id., ¶¶ 28-37.) Eventually, Taylor's team was able to address many of the Intromit problems and Applied commenced a full market release of the Intromit in July 2000. (Id., ¶ 38.) However, Taylor's team continued to work to find ways to improve the Intromit. (Id., ¶¶ 40-45.)

6. Applied's Initial Interest In Developing New HALS Devices.

25. In May 2000, Richard Ewers ("Ewers"), one of the named inventors on the Applied Patents, attended the American Urological Association ("AUA") meeting in Atlanta with Gary Dulak ("Dulak"), another one of the named inventors on the Applied Patents. (Ewers, ¶¶ 6-11; Dulak, ¶¶ 4-5.) Ewers was the director of engineering for the Urological Group at Applied. (Ewers, ¶ 3.) The Urological Group was separate from and operated independently of Taylor's group in the General Surgery Division. (Hilal, ¶ 59.) Dulak was also part of the Urological Group and reported to Ewers. (Dulak, ¶ 2.)

26. At the AUA meeting, Ewers and Dulak saw the Intromit. (Ewers, ¶ 12; Dulak, ¶ 5.) They determined that there must be a better way to design a HALS device, and they spent the return flight discussing possible designs. (Ewers, ¶¶ 13-14; Dulak, ¶ 6.)

27. Ewers began to experiment with creating HALS devices that used

elastomeric materials to seal. (Ewers, ¶¶ 16-17.) Ewers initially attempted to make a device from a material call C-flex, but had difficulty molding that material with the tools available at Applied. (Id., ¶¶ 17-19.)

7. Applied's Gel-Related Design Efforts.

28. As detailed below, the Court finds that between April 2000 and the August 31, 2000 animal lab session at Applied's facility, Applied personnel conceived all aspects of the Applied Patents, as reflected in the prototypes tested. The Court finds that the conception was solely the work of Applied personnel. The Court finds that there is adequate documentation to support the Court's conclusion of completed conception by August 31, 2000. Because the Court finds that none of the Gaya personnel are entitled to a finding of inventorship on the basis of contribution, the Court finds it unnecessary to outline in detail the contribution to conception made by each Applied named inventor. (See Court's Conclusions of Law, ¶ 24.) It is sufficient that the group completed conception on or before August 31, 2000.

29. Before reviewing Applied's development activities, the Court addresses Gaya's critique of the corroborating evidence. (See Gaya Proposed FF, ¶¶ 161-62.) Gaya fails to give due credit to the signed and dated laboratory and other notes (e.g., Exs. 7, 283, 863), but more importantly Gaya ignores the extensive collection of prototypes, gel moldings, wound retractors, and other components

which the present record establishes–albeit on the basis of testimony that they were created prior to August 31, 2000. (E.g., Brustad, ¶¶ 41-47.) Gaya challenges the fact that molds and other components were not themselves dated, but it does not contradict the unchallenged testimony as to when they were created. Nor does it challenge the extensive photographic evidence of the prototypes. (Brustad, ¶¶ 50-52.) A number of the photos are specifically described by Brustad as "in use during the animal lab session." (Id.; Ex. 898, 899.) That the corroboration evidence here is not a textbook example of the scientific method does not mean that it is insufficient.

30. In early 2000, Brustad, one of the named inventors on the Applied Patents, was working on ways to model abdominal wall tissue that could be used for testing devices, such as trocars. (Brustad, ¶ 35.) Brustad was the head of the Strategic Development Group at Applied. (Id., ¶ 6.) The Strategic Development Group was separate from and operated independently of Taylor's group in the General Surgery Division. (Hilal, ¶ 59.)

31. In April 2000, Brustad was shopping at a Best Buy in Mission Viejo on a weekend and came across a Fellowes keyboard wrist pad that was made of a soft, flexible material. (Brustad, ¶ 36.) Brustad thought the material might be suitable for simulating abdominal wall tissue. (Id.) When Brustad went to work on April 17, he sent another Applied engineer, Robert Bowes ("Bowes"), another named

inventor on the Applied Patents, back to the store to purchase the wrist pad.[4] (Id.)

32. Brustad cut open the wrist pad and discovered that it contained a gel material that was very soft and also pliable. (Id., ¶ 37.) Brustad was impressed with the material and began to consider uses beyond simulating abdominal wall tissue, such as using the material as a trocar seal. (Id.)

33. In May 2000, Brustad showed Ewers the gel material from the Fellowes wrist pad in the Urology lab. (Brustad, ¶ 39; Ewers, ¶ 20.) Ewers recognized the potential of using the material as a seal for a HALS device. (Ewers, ¶ 21.)

34. Ewers, Brustad, and Ed Pingleton ("Pingleton"), another named inventor on the Applied Patents, melted the gel material and discovered that it was possible to mold it into a desired shape. (Brustad, ¶ 40; Ewers, ¶¶ 21-26.) Ewers and Pingleton made an initial functional gel seal prototype on May 8, 2000. (Brustad, ¶ 41; Ewers, ¶ 28.) Ewers was able to stick his hand through the gel and observe that it was maintaining a seal. (Ewers, ¶¶ 26-27.)

35. The initial prototype is described in Ewers' lab notebook, and is signed and dated May 8, 2000. (Ex. 827, p. 23.) Ewers also included sketches of designs that could include a duckbill valve if needed to augment a zero seal, which is the

[4]Brustad also purchased another wrist pad on his own shortly thereafter. (Brustad, ¶ 38; Ex. 1021.)

seal that exists when no instrument is passing through the valve. (Ewers, Decl. ¶ 34; Ex. 827, p. 24.)

36. The day after the initial prototype was created, Brustad sent a sample of the gel to an outside company called Photometrics for analysis to help identify the material. (Brustad, ¶ 67; Ex. 826.) Brustad also sent an additional sample to Exxon Mobil in early June 2000 for analysis. (Brustad, ¶ 67; Ex. 847.)

37. Applied tasked the Urology Group with further development of the gel seal. (Ewers, ¶ 36; Hilal, ¶ 59.) As work progressed, others at Applied outside of the Urology Group began to work on the project. (Ewers, ¶ 43). These groups worked in the Strategic Development Group lab at Applied. (Hilal, ¶¶ 59-60.) This was a separate area from the R&D lab, where Taylor's group in the General Surgery Division worked. (Id., ¶ 60.)

38. At least Ewers, Brustad, and Pingleton worked on making prototypes from the gel material that were shaped like grommets or OREO® cookies. (Brustad, ¶ 43; see also Ewers, ¶¶ 47-52; Pingleton Dep., pp. 27:5-28:24.) Payam Adlparvar ("Adlparvar"), a named inventor on the Applied Patents, was also involved in developing gel seals with different shapes. (Adlparvar Dep., p. 100:9-18.) The team made the prototypes by preparing positive molds in the shape of the desired prototype and then making negative silicone molds in which the gel material was cast. (Brustad, ¶ 44; Ex. 838 (positive mold).) These designs had one

flange that would be positioned inside the abdomen and one flange positioned outside. (Ewers, ¶ 49.) A slit through the gel provided access into the abdomen. (Id., ¶¶ 51-52.) An example of a gel grommet prototype is shown below.

(Id., ¶ 40; Ex. 834.)

39. These prototypes eliminated the need for an adhesive to attach to the patient and provided the desired sealing with a simple, compact design. (Ewers, ¶ 41.) Ewers and Pingleton attended an animal lab with Dr. Clayman in mid-August 2000 to test some of these gel grommet prototypes. (Id., ¶ 50.) Following the testing, Ewers and others experimented with different variations of the grommet design, including preparing a prototype with a metal ring inserted into the bottom flange to provide greater stability. (Id., ¶ 51.) An example of a grommet prototype with a metal ring is shown below.

(Id.; Ex. 841.)

40. Other grommet designs were prepared with different gel properties, different dimensions, or with features such as areas configured to receive a wrist. (Ewers, ¶ 52.) Some of these features can be seen in photos of grommet prototypes shown below. Exhibits 839 and 843 both include an Applied logo molded into the gel, so they would have been created after Dulak came up with the idea to add the logo to the devices. (Brustad, ¶ 46.)

(Ewers, ¶ 52; Exs. 833, 835, 839, 843.)

41. During the development period, Dulak also began to research then-current HALS devices to learn about what was available on the market. (Dulak, ¶ 11.) He interviewed surgeons to learn more about desired product development inputs. (Id., ¶¶ 11-15.) Dulak concluded that a design would need several features: (1) it should seal without the use of an adhesive; (2) it should not require the use of a glove; and (3) the zero seal that blocks release of gas when no hand is through the device had to be combined with the hand seal and be connectable to a base. (Id., ¶ 18.) Dulak sketched an example of this concept on July 18, 2000. (Ex. 863.) Significantly, these critical design requirements were defined more than a month before receiving Gaya's new design proposal in late August. Although he previously testified that he made this sketch after visiting Dr. Schichman (Dulak, ¶¶ 19-20), Dulak acknowledged that he was mistaken and it was actually made the

day before meeting with Dr. Schichman. (Day 2 Tr., p. 191:15-19.) Although Dulak was clearly impeached, the Court draws no adverse credibility determination. The essential point is that he documented the design in mid-July 2000.

42. Dulak began to experiment with hybrid designs that included the use of a gel seal combined with a separate wound retractor. (Dulak, ¶ 8.) Dulak and Bowes also prepared various prototypes of these concepts. (See, e.g., Dulak, ¶¶ 28-29; Ex. 869 (prototype); see also Dulak, ¶ 25; Ewers, ¶ 43.) Rather than attaching the gel directly to a wound retractor, the gel was formed with a cap ring or collar that could attach to the wound retractor. (Dulak, ¶ 27; see also Ex. 863.) The photos below are of a prototype that includes a metal collar with a gel center. The parts for this and other prototypes were purchased on August 4, 2000. (Ex. 866 (Bowes expense report and receipts, including receipt at CV11-1406AM0067500 for several "4IN COLLAR[S]" from Home Depot), Ex. 869.)

(Dulak, ¶ 28; Ex. 870.)

43. Ensuring a proper connection between the gel and ring or collar was not a simple task. (Hilal, ¶ 70.) Members of the group considered different materials for the ring as well as different mechanical attachment means. (Id.) One option discussed was to have voids in the cap ring that would allow the gel to mechanically attach to the ring. (Id.) Brustad, Ewers, and Hilal worked on these ideas. (Id.)

44. Between July 2000 and August 2000, Dulak also experimented with concepts for wound retractors that would work well with the "gel cap." (Dulak, ¶ 30.) Aware of some of the difficulties with currently available wound retractors, Dulak developed a two-component wound retractor. (Id., ¶¶ 31-32.) One component included an inner ring (located inside the abdomen when in use) attached to a stretchy tubular sleeve material. (Id.) The second component was a base ring that rested on top of the patient's abdomen. (Id.) The base ring included upwardly extending hooks or tabs to which the proximal end of the tubular sleeve material could be attached. (Id.) The base ring also was designed so that the gel seal cap could be removably attached to it. (Id.)

45. Dulak made a prototype of the base-ring component in early August 2000, which he designed to use with the gel seal cap described above. (Id., ¶ 33; Ex. 869 (prototype of gel seal cap and base ring).) Photos of a prototype that uses this attachment mechanism are shown below.

(Dulak, ¶ 34; Ex. 869.)

46. The base ring prototype included a series of eight screws to which the tubular sleeve would be stretched over and attached. (Dulak, ¶¶ 33-35; Ex. 869.) It also included four red clips or snaps that were used to connect the gel seal cap to the base ring. (Dulak, ¶ 34.) In August 2000, Dulak also made several other retractor prototypes with a base ring to which a separate tubular sleeve could be attached. (Id., Dulak, ¶ 36; Exs. 873-876.)

47. Engineers with the Applied Strategic Development and Urological groups worked with additional aspects of the gel seals. For example, Adlparvar worked and experimented with different gel formulations that would provide the ideal properties to function as working seals. (Adlparvar Dep., p. 33:5-12; Ewers,¶

43; Brustad,¶ 60.) These properties included the ability to stretch without tearing. (Adlparvar Dep., p. 34:3-16.) These properties also included minimal tackiness. (Id., p. 24:11-19.)

48. Dulak also experimented with different gel compositions to determine the best consistency for use in a hand seal. (Dulak, ¶ 26; see also Ex. 882.) This work is reflected in laboratory notebook entries, signed and dated by Dulak between August 18, 2000 and August 30, 2000. (Ex. 882.) Determining the ideal composition and processing of the gel material was a challenging development effort that required large amounts of engineering time. (Dulak, ¶ 26.)

49. Applied engineers also contributed to improving the seals in other ways. They would have brainstorming sessions where multiple ideas be discussed. (Adlparvar Dep., p. 102:2-9; see also Bowes Dep., p. 27:18-25.)

50. Some of these sessions related to variations on the slit openings through the gel material and included Hilal, Brustad, Adlparvar, and others who brainstormed and tested different slit designs. (Hilal, ¶ 69; Brustad, ¶ 83.) The slit design was important because it could affect the seal provided and a condition referred to as "burping," whereby pressure building within the abdomen periodically opens the gel seal to release a portion of gas. (Hilal, ¶ 69; Brustad, ¶ 82.) It could also affect how easily and comfortably a surgeon could pass a hand through the device. (Pingleton Dep., pp. 34:23-35:15.) These individuals

conceived of gel openings, such as particular slit designs, that would improve sealing and minimize burping, allowing the gel seals to operate as desired. (Hilal, ¶ 69; Brustad, ¶ 84.)

8. Applied's GelPort Prototype Testing.

51. On August 31, 2000, Applied held an animal lab session so that the various teams could test their prototypes. (Dulak, ¶¶ 38-39.) Applied tested different gel seal concepts, including the grommet designs and the hybrid gel seal designs with different wound retractor prototypes. (Ewers, ¶¶ 56-59; Dulak, ¶¶ 38-48; Brustad, ¶¶ 48-60.) The animal lab testing was documented by photographs taken at the lab and by notes taken by Matt Petrine ("Petrine"), an Applied engineer. (Ex. 897 (notes); Ex. 304 at CV11-1406AM0183411 and Ex. 898 (photo of gel seal cap/wound retractor prototype); Ex. 304 at CV11-1406AM0183412 and Ex. 899 (photo of wound retractor prototype); Ex. 304 at CV11-1406AM0183425-26 and Ex. 906 (photo of grommet prototype); Ex. 304 at CV11-1406AM0183427-28 and Ex. 907 (photo of grommet prototype).)

52. The hybrid gel seal design concept performed particularly well at the animal lab session and generated excitement among the other engineers. (Dulak, ¶ 46; see also Ewers, ¶ 58.) Following the session, Dulak, Ewers, Bowes, and Brustad focused on finalizing that design. (Brustad, ¶ 60; Dulak, ¶ 49.) Brustad and Adlparvar also worked on refining gel formulations. (Brustad, ¶ 60.) By

October 2000, the team had prepared refined prototypes that were substantially similar to the original GelPort® product. (Dulak, ¶¶ 53-55; Ewers, ¶ 62.) These were tested at an animal lab session on October 12, 2000. (Ewers, ¶ 62.)

9. Other Prototype Testing.

53. Taylor's group tested other prototypes at the August 31, 2000 animal lab session, including some prototypes received from Gaya. (Taylor, ¶¶ 59, 61-72.) Those prototypes resulted from a phone conversation between Taylor and Rosney in which Rosney asked Taylor if he would be interested in seeing Intromit design improvement proposals. (Day 3 Tr., pp. 81:19-82:4.) Rosney followed up with a fax to Taylor on August 18 in which he informed Taylor that Bermingham would send the future development file for the Intromit. (Ex. 1224.) Taylor responded to ask if prototypes were available for testing at the August 31 animal lab session or, if there were no prototypes, if Rosney could send information sufficient for Applied to prepare prototypes for the lab. (Ex. 196.) Bermingham later sent an Intromit design improvement proposal to Taylor. (Ex. 886.) Applied received the design improvement proposal with two prototypes on August 28, 2000. (Taylor, ¶ 53; Ex. 337 (delivery receipt); Ex. 886; Ex. 197.)

54. The two prototypes that Applied received were of an Intromit sleeve attached to a separate wound retractor. (Taylor, ¶¶ 52-54, 57; see also Ex. 197 at CV11-1406AM0067714-67720; Ex. 886 at CV11-1406AM0067702-67712.)

These prototypes were both tested in the animal lab session. (Taylor, ¶ 69.)

55. Taylor's group also tested a prototype of a twist valve attached to a wound retractor. (Taylor, ¶ 64.) This twist valve was described in the file received from Gaya and the prototype was prepared by Morales. (Id.; see also Ex. 197 at CV11-1406AM0067721-67725; Ex. 886 at CV11-1406AM0067702.) The prototype was made by attaching two rings to opposing ends of a latex glove with the fingers removed. (Taylor, ¶ 64.) The rings were then twisted in opposite directions so that the latex would twist shut. (Id.) This was the same mechanism used in a commercially available HALS device called the Hakko LapDisc, described infra.

10. The Animal Lab Session Is Pivotal.

56. The animal lab session is a pivotal event in the Court's analysis of Applied's independent development of the Applied Patents. The Applied prototypes tested that day had several gel designs, which reflected the results of materials testing; used gel caps; included removably attached wound retractors; used a series of slit designs that resulted from development; and implemented a zero seal. All of this is documented in Petrine's notes of the session. (Ex. 897; see Dulak, ¶¶ 38-47.) In short, the prototypes reflected Applied's completed conception as of that date.

57. The exchange of information between Gaya and Applied between August 20, 2000 and the last day of the month does not change the Court's conclusions. First, Gaya was not advised of the animal lab until August 20. (Ex. 885.) Second, the Gaya design proposals were not received until August 28, 2000. (Exs. 197, 337.) Whether or not the design proposals in fact rose to the level of a contribution to the Applied Patents, discussed infra, there is no evidence that Applied incorporated the substance of the design proposals into the Applied prototypes tested at the animal lab session and, given the state of Applied's work by the end of August, it is not credible to believe that the Gaya proposals found their way into the Applied prototypes. The same is true of the Gaya prototypes tested at the animal lab session: They did not arrive until August 28, 2000. (Ex. 337.) Brustad, Dulak, and Ewers all testified that nothing from Gaya contributed to the inventions claimed in the Applied Patents. (Brustad, ¶ 86; Dulak, ¶ 4; Ewers, ¶ 6.) The sheer timing of events makes that testimony credible.[5]

58. Gaya points to the fact that prior to the animal lab session, Bermingham instructed Taylor how to construct a Gaya prototype using a twist valve for the animal lab session, and that Taylor instructed Morales to proceed to construct that prototype. (Gaya Proposed FF, ¶¶ 134-139.) Gaya also points to further work Morales did after the animal lab and his documentation. (Id., ¶¶ 150-58.) The Court agrees that Morales' subsequent work reflects the proposal disclosed by

[5]Gaya's suggestion that upon receipt of Gaya's prototypes and design proposals on August 28, 2000 Applied "MacGyvered up" its own prototypes using Gaya information is pure speculation. (See Gaya Proposed FF, ¶ 149.)

Gaya as reflected in his notebooks. (Id.) However, this ignores the more essential point that the Applied's prototypes which were tested already reflected completed conception, and Applied's prototypes did not incorporate Gaya's technology.

59. Gaya points to many events which occur after the animal lab session. (See, e.g., Gaya Proposed FF, ¶¶ 151-59.) But their significance is minimal given the Court's finding of conception by the date of the animal lab session.

11. Further Development.

60. Following the animal lab session, Taylor's group continued to work separately. (Taylor, ¶ 75.) One design that Morales worked on was a twist or iris valve similar to the Hakko LapDisc but that included a spring that automatically opened the valve to allow a hand to pass through and then retracted to seal the valve against the wrist. (Id., ¶ 76.) This design was an improvement over the Gaya twist valve with fixed rings, which was very difficult to pass a hand through. (Day 3 Tr., pp. 82:8-83:5.) This design was unrelated to the GelPort® development. (See Taylor, ¶¶ 75, 77.)

61. Taylor's group also considered further modifications to the Intromit, such as removing the adhesive flange and replacing it with a wound retractor component similar to that used in the prototypes that Gaya sent. (Id., ¶ 79; see also Day 3 Tr., pp. 84:17-85:11; Ex. 334.)

62. Taylor's group also worked on developing a locking mechanism that could connect a wound retractor to a hand seal cap. (Taylor, ¶ 78.) However, the group was never able to get a prototype to work satisfactorily. (Id.) Taylor's group also worked with adjustable wound retractor concepts after the August 31, 2000 animal lab session, none of which became a part of the GelPort® device. (Id.,¶ 80.) In November 2000, both Taylor and Morales discontinued work on HALS devices and focused on designing a new trocar seal. (Id.,¶ 84.)

63. The abandonment of Taylor and Morales' work after the animal lab session further underscores independence of Applied's conception and, assuming that Taylor and Morales benefitted from the Gaya proposal or exposure to the Gaya prototypes, the lack of any Gaya contribution to the Applied Patents.

12. The GelPort® Product.

64. The original GelPort® was introduced in June 2001. (Brustad, ¶ 104.) It was essentially the same as the prototype trialed at the October 12, 2000 animal lab session. (Ewers, ¶ 62; see also Dulak, ¶¶ 53-55.) The superior performance of the GelPort® led to its rapid acceptance. (Hilal, ¶ 83.) Eventually, Applied's Intromit customers started converting to the GelPort® product. (Id.) Demand for the Intromit eventually dwindled to close to nothing, and Applied was forced to scrap its remaining Intromit devices. (Id., ¶ 85)

13. Applied's Provisional Application.

65. In September and October 2000, all Applied engineers working on HALS concepts were encouraged to submit invention disclosures to the Applied legal department. (Taylor, ¶ 81.) Applied planned to file a provisional patent application that included everything tested at the lab as well as concepts that had been considered but not yet tested. (Brustad, ¶ 87.) This would work as a way to "save the date" for future patent applications directed to specific concepts. (Id.)

66. Applied filed a provisional patent application on October 19, 2000 that included disclosures relating to Applied's new HALS concepts, among other things. (Ex. 16.) The provisional patent application listed the following individuals as inventors: Brustad, Ewers, Pingleton, Hilal, Adlparvar, Taylor, Dulak, Michael Dunn ("Dunn"), Morales, and Charles Hart ("Hart"). (Id.) The provisional application included no claims. (See id.)

67. The provisional patent application was divided into five different sections. The first section is titled "Gel Seal Apparatus And Method." (Id. at COVX0123990.) It relates to the work done by Brustad, Ewers, Bowes, Dulak, Adlparvar, Hilal, and Pingleton in discovering and developing different gel seals for use with HALS devices. (See id. at COVX0123990-4008.)

68. The second section is titled "Additional Gel And Non-Gel Seal-

Apparatus And Method." (Id. COVX0124009.) This section includes the hybrid gel seal and retractor concepts developed by at least Dulak and Bowes. (See id. at COVX0124009-47.) It also includes the spring-biased twist valve that Morales worked on. (See id.; see also Taylor, ¶ 83; Day 3 Tr., pp. 85:12-86:10.)

69. The third section is titled "Wound Retractor For Use With Hand Assisted Laparoscopic Surgery." (Ex. 16 at COVX0124048.) This section included wound retractor concepts developed by Taylor. (See id. at COVX0124048-88.)

70. The fourth section is titled "Peritoneal Cavity Illumination With Hand Assisted Laparoscopic Devices." (Id. at COVX0124090.) The fifth section is titled "Sealed Surgical Access Device." (Id. at COVX0124093.) The fourth and fifth sections are unrelated to the work done by Taylor's team or the teams that worked on the gel seal.

B. Applied's Patents.

71. On September 21, 2001, Applied filed PCT Application No. PCT/US01/29682, which claimed priority to the provisional application and included the subject matter from the first and second sections of the provisional application that came from the inventors named on the Applied Patents. (Ex. 989.) The PCT application did not include subject matter from the other sections of the

provisional application. (See id.) The PCT Application listed the following individuals as inventors: Ewers, Brustad, Pingleton, Hilal, Dulak, Adlparvar, and Bowes. (Id.) All of the Applied Patents trace priority back to this PCT application.

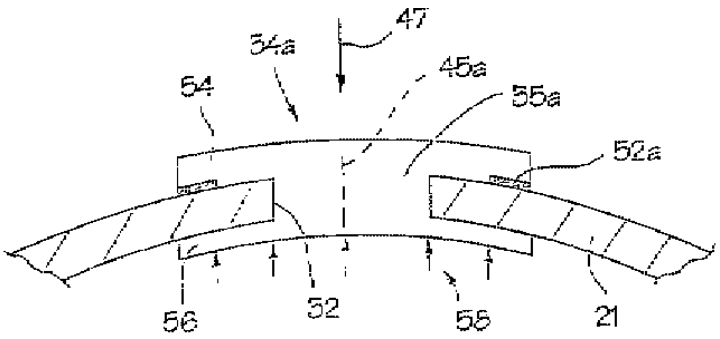
72. Two other PCT applications were filed that included other subject matter included in the provisional application. PCT Application No. PCT/US01/50160 was filed on October 20, 2001, and listed Ewers, Brustad, Pingleton, Hilal, Adlparvar, Taylor, Dulak, Dunn, Morales, Hart, and Bowes as inventors. (Ex. 990.) PCT Application No. PCT/US01/50742 was also filed on October 20, 2001, and listed the same inventors. (Ex. 991.) Like the above, these PCT applications did not include any drawings or descriptions from the provisional application relating to the spring-biased twist valves. (Compare Ex. 16 with Exs. 990, 991.) None of the Applied Patents traces back to these two PCT applications.

1. Overview Of The Inventions Described In The Applied Patents.

73. The disclosures of the Applied Patents relate generally to devices facilitating sealed access with surgical instruments, such as a surgeon's hand, across a body wall and into a body cavity. (Ex. 1, col. 1, lines 23-26.) In the case of laparoscopic surgery, the abdominal cavity can be insufflated with a gas to increase the volume of the working space within the cavity. (Id., col. 4, lines 36-40.) The patent describes embodiments of an access device that has the general

configuration of a pad. (Id., col. 5, lines 20-21.) Figure 2 of the patent depicts one of the earliest conceptions of a gel pad seal that originated with the work of Ewers and Brustad using the Fellowes wrist pad, and Figures 3 and 4 represent variations of that concept. (Brustad, ¶¶ 89-90.)

74. The pad can have a variety of forms, such as pads designed to be positioned within an incision and that have an external flange and an internal flange. (Ex. 1, col. 6, lines 7-9.) Figure 6 of the patent, reproduced below, illustrates on embodiment of such a pad.



75. Figure 6 of the patent shown above, as well as Figures 4 and 7-11, depict "grommet" designs from the early conception made by Ewers, Pingleton, and Brustad using the Fellowes wrist pad gel material. (Brustad, ¶¶ 90-91.) In one described embodiment, an adhesive ring can form a seal between the pad and the abdominal wall; alternatively, a radial seal can be formed by surface contact between flanges (elements 54, 56) and the abdominal wall, or an axial seal can be formed by pressure from the abdominal wall against the pad. (Ex. 1, col. 6, lines

25-43.) An opening 45a can extend through the pad to define a working channel. (Id., col. 6, lines 22-24.) In the absence of an instrument inserted through the pad, in one embodiment the opening closes against itself to form a zero seal and prevent the escape of insufflation gases. (Id., col. 6, lines 59-62.) When an instrument is inserted through the opening, an instrument seal is formed between the material of the access device or pad and the instrument. (Id., col. 6, lines 62-66.)

76. The grommet type designs shown in Figures 9 and 10 of the patent include additional reinforcing o-rings (elements 61 and 65 in the figures). (Id., col. 9, line 54 to col. 10, line 12.) This is similar in concept to the prototype of Exhibit 841 made by the Applied inventors that consisted of a grommet design with a metal ring inserted. (Exs. 841, 842; Ewers, ¶ 51; Brustad, ¶ 92.)

77. The patent also describes a variety of lead-in cavities that can be formed on an external surface of the access device and communicate with the opening or slit. Figures 12-14 illustrate embodiments with a cylindrical lead-in cavity 72 with a trapezoidal slit 45e. (Ex. 1, col. 10, lines 51-59.) These are similar to the prototypes of Exhibits 833 and 835 made by Applied inventors, which each have a cylindrical lead-in and a trapezoidal slit. (Exs. 833-836; Brustad, ¶¶ 46, 93.) Figures 15 and 16 show a variation of the designs shown in Figures 12-14, but also include gel that extends further distally to form a "duck-bill" type structure (element 74) with the gel. (Ex. 1, col. 10, line 65 to col. 11, line 21). The prototypes of Exhibits 833 and 835 made by the Applied inventors each included

this feature. (Exs. 833-836; Brustad, ¶ 94.)

78. Other designs include, for example, lead-in cavities that are cylindrical or in the form of an inverted cone. (E.g., Ex. 1, col. 10, lines 55-57; col. 11, lines 42-44.) The patent describes how the shape of the slit can also be modified. It identifies, among other possibilities, trapezoidal configurations, angled slits, multiple slits formed in individual planes spaced with respect to each other, and slits having a configuration that is curved, sinusoidal, or S-shaped. (Id., col. 10, lines 58-59; col. 12, lines 19-20, 27-29, and 37-39; col. 13, lines 1-4.)

79. The patent also describes embodiments in which slits do not extend completely to a central axis of a pad, thus forming an axial channel. (Id., col. 12, lines 47-51.) In some embodiments, this channel can be left open and a zero seal might be provided by an additional valve. (Id., col. 12, lines 56-58.)

80. Figures 17 and 18 of the patent show two-layer valves with a gel pad outer-layer and a base, which is a second layer supporting the gel pad. (Id., col. 11, lines 22-38.) In this configuration, a duck-bill type valve (element 74) may extend distally from the base portion. This design is reflected in one of Ewer's lab notebooks. (Ex. 827; Ewers, ¶ 34.)

81. The patent highlights how these various features may particularly depend upon the material that forms the access device. (Ex. 1, col. 7, lines 42-45.)

The patent then devotes a number of columns to describing aspects of various materials, including: material formulations such as KRATON/oil mixtures, KRATON/oil mixtures with a mineral oil, other tri-block polymers, ratios of styrene to rubber contents, di-block polymers, various base formulas alloyed with one another, the use of foaming agents, and additives to further modify material properties; particular elongation and durometer characteristics; manufacturing processes; and layering techniques to provide different properties in each layer. (See generally id., col. 7, line 45 to col. 9 line 45.)

82. The patent describes an embodiment that uses a duck-bill valve to further enhance characteristics of the zero seal. (Id., col. 11, lines 5-7.) The patent also describes an embodiment in which a base, which might be formed of a material more rigid than the pad, can partially surround the pad, including its distal surface. (Id., col. 11, lines 22-33.)

83. The patent also describes other embodiments that include a gel cap 143, a base 145, and a retraction sheath 147, such as in the embodiment reproduced below, which corresponds generally to Applied's original commercial GelPort® product and prototypes made leading to that product. (Id., col. 14, lines 2-4; Brustad, ¶ 100; Dulak, ¶¶ 25-37, 41.)

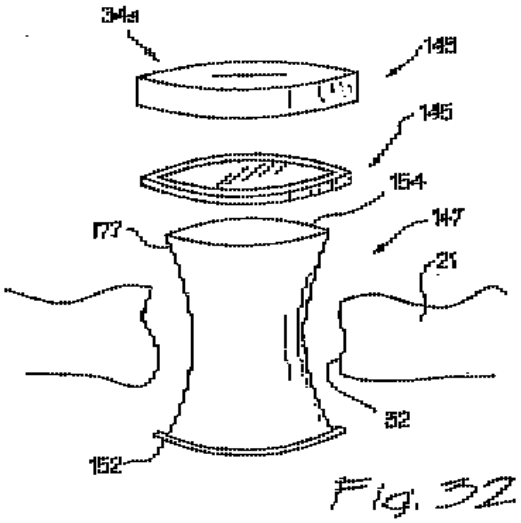


Fig. 32

84. The patent describes a gel cap as including a gel pad 35s and a circumferential cap ring 154. (Ex. 1, col. 14, lines 5-7.) The gel cap can form a seal with the base to define a working channel through the pad, the cap ring, the base, and the retraction sheath 147. (Id., col. 14, lines 7-10.) As previously described in the patent, the gel pad can provide both a zero seal and an instrument seal for a wide range of instrument diameters. (Id., col. 14, lines 10-13.)

85. The patent again highlights materials that can be used, referencing the possibilities previously discussed in the specification. (Id., col. 14, lines 22-24.) The patent describes how the cap ring material can be formulated in such a way that it is more rigid than the gel pad while maintaining a material interface between the pad and the ring. (Id., col. 14, lines 22-27.)

86. The patent also describes the retraction sheath. It can include a tubular wall with a flexible retaining ring 152 at its distal end and a fold 154 at its proximal end. (Id., col. 14, lines 54-60.) The patent also describes the materials of the retraction sheath, which are formed of an elastomer, such as neoprene, in a preferred embodiment. (Id., col. 14, lines 62-65.) In use, the retaining ring can be compressed and fed through the incision. (Id., col. 15, lines 39-40.) The sheath can be stretched to retract the incision and then pulled over the base. (Id., col. 14, line 66 to col. 15, line 10.)

2. U.S. Patent No. 7,473,221.

87. Applied filed the application for the '221 patent on September 21, 2001 as a National Stage application of PCT Application No. PCT/US01/029682. (Ex. 40.) The '221 patent shares the same specification as the PCT application and lists the same inventors. (Id.) Inventor declarations signed by the named inventors were submitted during prosecution of the '221 patent. (Ex. 17 at COVX124192-95.)

88. The '221 patent has three independent claims: claims 1, 6, and 21. (See Ex. 40.) They are directed generally toward an access device with a gel-based valve structure and a supporting cap ring or gel support structure adapted to be attached to an incision seal support structure or wound retractor. (Id.) The valve forms a seal in the absence of an instrument through the valve and with an

instrument inserted through the valve. (Id.) The seal with the instrument is formed between the gel and the instrument. (Id.) The claims recite various features of the gel valve structure. For example, the independent claims recite, among other features, "a valve structure comprising an unencapsulated gel material" (Claim 1); "a gel cap comprising an ultragel" (Claim 6), which is defined as having "an ultimate elongation greater than about 1000 percent and a durometer less than about 5 Shore A" (see Ex. 1, col. 8, lines 56-59); and a "valve structure comprising a gel material . . . the gel mateiral comprises an elastomeric oil mixture" (Claim 21). (See Ex. 40, col. 18, lines 30-45.)

89. The inventions claimed in the '221 patent are reflected in the work of Ewers, Brustad, Pingleton, Bowes, Hilal, Dulak, and Adlparvar. For example, contributions to the claimed gel material that could seal with and in the absence of an instrument came from the teamwork of Ewers, Brustad, Pingleton, Dulak, Adlparvar, and Hilal. (E.g., Ewers, ¶ 28 (describing making initial gel prototypes with Pingleton); Brustad, ¶ 60 (describing work with Adlparvar in developing gel formulations); Dulak, ¶ 26 (describing work with gel compositions to determine best consistency for sealing); Hilal, ¶¶ 69-70 (describing developing ideas for slit configurations to maintain a zero seal and means to facilitate connection of gel to a cap ring).) Also, at least Dulak and Bowes contributed to gel-based valves that could attach to wound retractors. (See, e.g., Ex. 863; Dulak, ¶ 25.) The '221 patent itself is also documentation of the contributions of the named inventors to the claimed inventions.

3. U.S. Patent No. 7,481,765.

90. Applied filed the application for the ‘765 patent on October 5, 2005 as a continuation of the ‘221 patent. (Ex. 8.) The ‘765 patent shares the same specification as the ‘221 patent and lists the same inventors. (Id.) The inventor declarations from the ‘221 patent were submitted with this application. (See Ex. 18 at COVX124797-800.)

91. The ’765 patent has three independent claims: claims 1, 14, and 21. (See Ex. 8.) They are directed generally toward an access device having a valve with two layers, one of which is a gel material. (Id.) The gel layer forms a seal in the absence of an instrument through the valve and also forms a seal with an instrument inserted through the valve. (Id.) The valve can accommodate a range of instrument sizes. (Id.)

92. The inventions claimed in the ‘765 patent are reflected in the work of Ewers, Brustad, Pingleton, Bowes, Hilal, Dulak, and Adlparvar. For example, contributions to the claimed gel material that could seal with and in the absence of an instrument came from the teamwork of Ewers, Brustad, Pingleton, Dulak, Adlparvar, and Hilal. (E.g., Ewers, ¶ 28 (describing making initial gel prototypes with Pingleton); Brustad, ¶ 60 (describing work with Adlparvar in developing gel formulations); Dulak, ¶ 26 (describing work with gel compositions to determine best consistency for sealing); Hilal, ¶ 69 (describing developing ideas for slit

configurations to maintain a zero seal).) Additionally, the two-layer valve is reflected in the work done by Ewers, as documented in his lab notebook. (Ex. 827 at CV11-1406AM0067397.) The '765 patent itself is also documentation of the contributions of the named inventors to the claimed inventions.

4. U.S. Patent No. 8,105,234.

93. Applied filed the application for the '234 patent on January 27, 2009 as a continuation of the '765 patent. (Ex. 667.) The '234 patent shares the same specification as the '221 patent and lists the same inventors. (Id.) The inventor declarations from the '221 patent were submitted with this application. (See Ex. 19 at COVX125088-91.)

94. The '234 patent has two independent claims: Claims 1 and 13. (See Ex. 667.) They are directed generally toward a surgical hand port having a gel seal valve that includes a support ring and a gel pad. (Id.) The gel pad forms a seal in the absence of an instrument through the gel pad and also forms a seal with an instrument inserted through the gel pad. (Id.) The gel pad can accommodate a range of instrument sizes. (Id.)

95. The inventions claimed in the '234 patent are reflected in the work of Ewers, Brustad, Pingleton, Bowes, Hilal, Dulak, and Adlparvar. For example, contributions to the claimed gel material that could seal with and in the absence of

an instrument came from the teamwork of Ewers, Brustad, Pingleton, Dulak, Adlparvar, and Hilal. (E.g., Ewers, ¶ 28 (describing making initial gel prototypes with Pingleton); Brustad, ¶ 60 (describing work with Adlparvar in developing gel formulations); Dulak, ¶ 26 (describing work with gel compositions to determine best consistency for sealing); Hilal, ¶¶ 69-70 (describing developing ideas for slit configurations to maintain a zero seal and means to facilitate connection of gel to a cap ring).) Also, at least Dulak, Bowes, Brustad, Ewers, and Hilal contributed to gel-based valves that had a cap ring. (See, e.g., Ex. 863; Dulak, ¶¶ 25-27; Hilal, ¶ 70.) The '234 patent itself is also documentation of the contributions of the named inventors to the claimed inventions.

5. U.S. Patent No. 8,016,755.

96. Applied filed the application for the '755 patent on December 3, 2010 as a continuation of the '234 patent. (Ex. 1.) The '755 patent shares the same specification as the '234 patent and lists the same inventors. (Id.) The inventor declarations from the '221 patent were submitted with this application. (See Ex. 20 at COVX125484-89.)

97. The '755 patent has three independent claims: Claims 1, 9, and 17. (See Ex. 1.) Claims 1 and 9 are directed generally toward a surgical access device that includes a flanged and monolithic pad or seal that is inserted into an incision, seals with the abdominal wall, and has an opening or access channel that can seal with

an instrument inserted through the opening or access channel. (Id.) Claim 17 is directed generally toward a method of using a surgical access device that includes a flanged and monolithic seal that is inserted into an incision, seals with the abdominal wall, and has an access channel that can seal with an instrument inserted through the access channel. (Id.) The claims further recite specific materials from which the access pad or access seal is made. (Id., e.g., at Claim 1 (triblock copolymer, oil, foaming agent mixture), Claim 8 (an SEBS triblock copolymer), and Claims 12-16, 18.)

98. The inventions claimed in the '755 patent are reflected in the work of Ewers, Brustad, Pingleton, Bowes, Hilal, Dulak, and Adlparvar. For example, at least Ewers, Brustad, and Pingleton developed grommet-type seals that included flanges and were inserted into an incision. (Brustad, ¶ 43; see also Ewers, ¶¶ 47-52.) Claim 11 of the '755 patent also includes a requirement that at least one of the access channels self-seal in the absence of an instrument. (See Ex. 1.) Contributions to the claimed materials that could seal with and in the absence of an instrument came from the teamwork of Ewers, Brustad, Pingleton, Dulak, Adlparvar, and Hilal. (E.g., Ewers, ¶ 28 (describing making initial gel prototypes with Pingleton); Brustad, ¶ 60 (describing work with Adlparvar in developing gel formulations); Dulak, ¶ 26 (describing work with gel compositions to determine best consistency for sealing); Hilal, ¶¶ 69-70 (describing developing ideas for slit configurations to maintain a zero seal and means to facilitate connection of gel to a cap ring).) The '755 patent itself is also documentation of the contributions of the

named inventors to the claimed inventions.

6. U.S. Patent No. 8,496,581.

99. Applied filed the application for the '581 patent on March 15, 2012 as a continuation of the '755 patent. (Ex. 729.) The '581 patent shares the same specification as the '755 patent and lists the same inventors. (Id.) The inventor declarations from the '221 patent were submitted with this application. (See Ex. 138 at CV11-1406AM0185387-92.)

100. The '581 patent has three independent claims: Claims 1, 12, and 21. (Ex. 729.) They are directed generally toward a surgical access device that includes a non-inflatable, flanged and monolithic access port that can span the thickness of a patient's abdominal wall and that seals against the abdominal wall and with an instrument inserted through the port. (Id.)

101. The inventions claimed in the '581 patent are reflected in the work of Ewers, Brustad, Pingleton, Bowes, Hilal, Dulak, and Adlparvar. For example, at least Ewers, Brustad, Dulak and Pingleton developed grommet-type seals that included flanges and were inserted into an incision. (Brustad, ¶ 43; see also Ewers, ¶¶ 47-52.) Claim 17 of the '581 patent also includes a requirement that the opening self-seal in the absence of an instrument. (Ex. 729.) Contributions to the claimed materials that could seal with and in the absence of an instrument came

from the teamwork of Ewers, Brustad, Pingleton, Dulak, Adlparvar, and Hilal. (E.g., Ewers, ¶ 28 (describing making initial gel prototypes with Pingleton); Brustad, ¶ 60 (describing work with Adlparvar in developing gel formulations); Dulak, ¶ 26 (describing work with gel compositions to determine best consistency for sealing); Hilal, ¶¶ 69-70 (describing developing ideas for slit configurations to maintain a zero seal and means to facilitate connection of gel to a cap ring).) The '581 patent itself is also documentation of the contributions of the named inventors to the claimed inventions.

C. Gaya Did Not Contribute To Inventions Claimed In The Applied Patents.

1. Gaya Has Failed To Show That Communications Of Future HALS Design Concepts Occurred During The March 2000 Meeting In Ireland.

102. Bermingham testified that on the second day of Taylor and Johnson's visit, they "discussed future design concepts for the HALS devices." (Bermingham, ¶ 43.) According to Bermingham, he paged through two handwritten lab notebooks with Taylor and Johnson. (Day 1 Tr., pp. 131-32.) Bermingham and Rosney also testified that they demonstrated certain prototype HALS devices on a simulator. (Bermingham, ¶ 44; Rosney, ¶ 49.) Taylor and Johnson deny that the parties discussed future HALS design concepts or that

Bermingham and Rosney demonstrated prototype HALS designs during the March 2000 visit to Ireland. (Johnson, ¶ 30; Taylor, ¶ 23.) The Court resolves the factual dispute in favor of Taylor and Johnson.

103. Taylor and Johnson's testimony that future design concepts for HALS devices were not discussed at the March meeting is credible. Gaya presented no evidence to corroborate its allegation that Bermingham and Rosney shared future HALS design concepts with Johnson and Taylor during the visit. Bermingham did not record the March meeting in any way, and he does not believe that anyone at Gaya made any written memorandum of what happened during the visit. (Day 1 Tr., p. 130:7-12.) Rosney was aware of no documents to the present that confirm that Bermingham showed lab notebooks to Applied during the March 2000 meeting. (Id., pp. 147:24-148:3.) Rosney believes he may have taken notes in his diary regarding the March 2000 meeting with Johnson and Taylor, but does not believe there is any documentary source he could consult to refresh his recollection of what happened at the meeting because his diaries were thrown out. (Id., pp. 170:4-171:7.)

104. To the extent that the document flow between Applied and Gaya and between Gaya and its advisors allows the Court to take a back azimuth as to what occurred, the analysis does not support a finding of disclosure, and indeed leads to the opposite conclusion. The available evidence corroborates the testimony of Johnson and Taylor that future concepts were not the subject of the meeting.

105. The agenda for the meeting corroborates the testimony of Johnson and Taylor that the purpose of the meeting was to review the Intromit manufacturing process and discuss shipping to consider the transfer of the manufacturing equipment to Applied. (See Exs. 803, 805.) Taylor sent a draft of the agenda to Rosney on March 15, 2000. (See Ex. 803.) It did not mention future HALS concepts. (Id.) Ex. 805 is a later version of the agenda with additional items, but it likewise contains no reference to any future HALS concepts. (Ex. 805 at GAYAX0009361 (Rosney fax of revised agenda sent by Rosney to Caldwell and Hugh MacGiollaRi dated March 22, 2000).) The revised agenda also included notes made by Caldwell. (Day 1 Tr., p. 145:19-146:10.) Rosney testified that before the March 2000 meeting with Applied he spoke with Caldwell about discussing future concepts with Applied. (Id., pp. 144:24-145:1.) But the agenda for the meeting makes no reference to any future concepts. (Id., p. 145:11-14.) And even after Gaya made notes on the agenda and sent it back to Applied, there still was no mention of future concepts. (Id., p. 147:20-23.)

106. The only notes available from the March 2000 meeting were kept by Taylor. His notes discuss manufacturing and shipping for the Intromit. (Ex. 807.) They do not mention anything about new design concepts. (Id.) Taylor also took photographs during both days of the visit. (Taylor, ¶ 15; Johnson, ¶ 19.) These photographs only show manufacturing equipment and the process of making Intromit devices. (Exs. 810, 811.) They do not show prototypes, notebooks, or anything else to corroborate the testimony of Bermingham or Rosney.

107. Taylor took sixty-five photos of the making of Intromit devices on the second day of the visit. (Exs. 810, 811; see also Day 3 Tr., p. 79:11-21 (time stamps on electronic files of photos confirm taken on second day); Taylor, ¶ 15 (two photos from Exhibit 810 taken second day).) This is the same day that Bermingham testified was spent reviewing notebooks and demonstrating prototypes. (Bermingham, ¶¶ 43-54.)

108. The requirements of the Secrecy Agreement between Applied and Gaya at the time place in question the testimony of the Gaya witnesses. The Secrecy Agreement specified that any information disclosed in writing must be marked confidential to be protected under the agreement. (Ex. 4, ¶ 4.) The Agreement also required that if any confidential information was disclosed verbally or in non-written form, the disclosing party was required to summarize the information in writing, identify the information as confidential, and transmit it to the other party within thirty days in order for the information to be protected under the agreement. (Id.) Gaya never documented what it contends was disclosed to Applied at the March meeting in Ireland. The Court finds this significant.

109. Having drafted and signed the Secrecy Agreement, Caldwell was aware of these provisions. (Caldwell, ¶ 38.) At least by August 2000, Bermingham also was aware of these provisions because he sent design improvement proposals to Taylor and marked the proposals as confidential with reference to the Secrecy Agreement. (Ex. 197 at CV11-1406AM0067713.) Thus,

Caldwell's testimony that he gave permission to share future HALS design concepts to Johnson and Taylor on the understanding that such disclosure was made pursuant to the Secrecy Agreement, without also requiring written documentation as required by the terms of the Secrecy Agreement, is not credible. (See Caldwell, ¶ 53.) This is particularly true given that Caldwell, a lawyer, required Johnson and Taylor to sign a non-disclosure agreement before showing them the Introcar product during the same visit. (See Ex. 809.)

110. Bermingham's testimony regarding the March 2000 meeting is inconsistent with the testimony of Taylor, Johnson, and Rosney. Bermingham testifies that he went through a detailed review of Gaya lab notebooks LN-001 and LN-002 with Johnson and Taylor. (Bermingham, ¶ 53.) Bermingham claimed to have a vivid memory of this meeting, even comparing it to memories he had of September 11th. (Day 1 Tr., pp. 133:3-134:2.) According to Bermingham, Rosney was present during the review of lab notebooks. (Bermingham, ¶ 53.) Rosney, however, does not recall any lab notebooks being shown to Taylor and Johnson. (Day 1 Tr., pp. 143:8-18, 169:23-170:3 (not present for Bermingham paging through lab notebooks with Taylor and Johnson).) Taylor and Johnson also testified that no notebooks were shown to them. (Taylor, ¶ 23; Johnson, ¶¶ 30-31.)

111. Documents between Gaya and Applied following the March 2000 meeting in Ireland do not mention any disclosure of future HALS concepts to Applied at that meeting although the subject matter and context of the documents

would have logically referenced the March 2000 disclosure of future HALS concepts if such had occurred.

112. First, in August 2000, Bermingham sent a document to Taylor of Applied titled "Intromit Design Improvement Proposals." (Ex. 197.) The document included two proposed designs. Proposal No. 1 was an "Intromit Sleeve with Separate Wound P/R. (Id. at CV11-1406AM0067714.) Proposal No. 2 was a "Wound Protector/Retractor with Twist Valve Attachment." (Id. at CV11-1406AM0067721.) Even though these were the same design concepts that Bermingham testified he demonstrated for Taylor and Johnson in March 2000, Bermingham makes no mention of any March 2000 demonstration. (Day 1 Tr., p. 67:10-16.) According to Bermingham, the March 2000 demonstration probably lasted an hour or two. (Id., p. 67:17-20.) It is reasonable to expect that the August 2000 proposal would have included at least some mention that the proposed designs had been previously demonstrated for Taylor if that had been the case.

113. Rather than making any mention of the prior March 2000 demonstration, the August 2000 proposal document appears to be written on a clean slate. For example, Proposal No. 1 included a section titled "Advantages of Proposed Design," which sets forth advantages that Bermingham testified were the subject of the March 2000 meeting. (Id., p. 68:1-9; see also Ex. 197 at CV11-1406AM0067717 (listing various advantages of the proposals).) He makes no mention of the fact that these were advantages allegedly discussed or

recognized in March. (Day 1 Tr., pp. 68:10-69:9.)

114. Similarly, the discussion of Proposal No. 2 states: "The twist valve proposal was trialed on 19/03/99, LN-001. It was confirmed that the use of the twist valve mechanism as the primary seal for a hand access port looked extremely promising, but would require a lot of further development." (Ex. 197 at CV11-1406AM0067722.) That this document refers back to a trial in 1999 but makes no mention of a demonstration for Taylor and Johnson in March 2000 suggests the March 2000 demonstration did not occur.

115. Bermingham also sent a cover memo with the August 2000 proposal. (Ex. 886 at CV11-1406AM0067702.) The cover memo refers to the proposals that Bermingham testified he demonstrated for Taylor and Johnson in March 2000, but it includes no reference to any March 2000 demonstration. (Id.; Day 1 Tr., pp. 69:20-22.) The cover memo also proposes a meeting to Taylor that would have been a duplication of the meeting that Bermingham testified already occurred in March 2000. (Ex. 886 at CV11-1406AM0067702.)

116. The cover memo also includes information that would have been known to Taylor had the meeting in March of 2000 occurred as Bermingham testified. Specifically, Bermingham stated in the cover memo: "It may be of benefit to organise a meeting between Applied and [Gaya] if you want to proceed with significant design changes such as those proposed for the Intromit Product, as

I have spent a considerable amount of time developing viable design solutions to improve the Intromit Product. A number of options have been eliminated to date." (Id.) Had the meeting in March 2000 actually occurred as Bermingham now testifies, this information would have been known to Taylor. (Day 1 Tr., pp. 70:2-71:12.)

117. Correspondence from Bermingham to Gaya's lawyer on October 20, 2000 also demonstrates the same pattern of omission. (Ex. 680.) Specifically, Bermingham and Rosney sent a fax letter to a Gaya lawyer regarding the Applied product that Caldwell and Hugh MacGiollaRi ("MacGiollaRi") had seen during their October 2000 visit to Applied. (Id.) The fax letter states, "As requested by Hugh [MacGiollaRi], we have looked at the sketch for the Applied Port, and have the following comments to make. See Attached." (Ex. 680 at GAYAX0003652.) In the attached memo, Bermingham and Rosney referred to the design proposals sent to Applied in August 2000, but they make no mention of having reviewed any design proposals with Applied in March 2000. (Ex. 680; Day 1 Tr., p. 92:11-15.) Had Bermingham and Rosney actually demonstrated the prototypes to Johnson and Taylor in March 2000, it would have been natural for them to include such information in this memo.

118. The third instance in which Bermingham drafted a document that did not mention any March 2000 disclosure of future HALS concepts to Applied occurred on December 10, 2001 when Bermingham sent a letter to Caldwell

summarizing information Gaya had provided to Applied. (Ex. 679.) This letter references the design proposal report of August 24, 2000 and a telephone conversation of August 29, 2000. (Id.) The letter makes no mention of any information provided to Applied at a meeting in March 2000. The letter provides detail of the conversation of August 29, 2000. (Id,) These details are substantially the same as what Bermingham testified was discussed earlier in March 2000. (Day 1 Tr., p. 94:11-17.) If these topics had been discussed in March 2000 as Bermingham so testified, it is not logical to then have a telephone conversation on these same topics in August. Further, if these topics had been discussed in March 2000 as Bermingham so testified, it is not logical to then record the fact of a telephone conversation on the topics, such as in Exhibit 679, and yet make no mention of the extensive discussion on the same topics that had occurred in March 2000.

119. It is perhaps understandable that some of the correspondence after March would not specifically reference the March disclosures. That none of it references the March disclosures is not understandable, and raises an inference that there were no disclosures in March.

120. In providing its summary of evidence concerning the March 23-24 meetings, Gaya cites no documentary evidence to support its assertion of the disclosure of the Gaya notebooks. (See Gaya Proposed FF, ¶¶ 506-16.)

121. Gaya seeks to draw an inference that Applied had access to Gaya design information based upon the perceived similarities that Gaya identifies between various sketches from its notebooks and drawings in Applied's provisional application. This inference is not supported.

122. For example, as described infra, wound retractors were known in the art. This includes adjustable wound retractors with an internal ring, an external ring, and a connecting sleeve. (See, e.g., Ex. 951 (Dexterity Protractor); Ex. 935 (LapDisc product); Ex. 357 (Kaji '426 patent).) This also includes retractors that could removably attach to valve elements. (See, e.g., Ex. 762 (Beane '577 patent); Ex. 352 (MacLeod '298 patent).) So it is not surprising that designs having valves attached to wound retractors may be found in Gaya's and Applied's documents.

123. The iris valves that appeared in Applied's provisional patent application were different from the twist valve designs that Bermingham sent Taylor in late August 2000. (Day 3 Tr., pp. 85:12-86:10 (Taylor explaining iris valves in provisional application included mechanism for automatically opening and closing the valve).)

124. Gaya also cites to similarities between flanged designs in Cummins' personal notebook and flanged designs in Applied's provisional application. But there is no testimony that Cummins' personal notebook or the flanged designs sketched in the notebook were communicated to Applied.

125. Thus, any similarity between such drawings does not demonstrate that Gaya shared any of its concepts with Applied during Applied's visit in March 2000. This is particularly true in view of the overwhelming evidence to the contrary.

126. Gaya also cited the term "flubber" that appears in Applied's provisional application as if the term came from Gaya. The term "flubber" came from a series of popular movies (the 1961 Disney movie titled "The Absent Minded Professor" and the 1997 movie remake titled "Flubber") in which it was used to describe a material discovered in the movies. Indeed, Cummins testified that his use of the term was based on those movies. (Cummins, ¶ 24; Day 1 Tr., p. 176:7-10.) However, the only Gaya document in which the term appears is Cummins' datebook (Ex. 158 at GAYAX0008761), and Cummins testified that he did not show his datebook to Applied. (Day 1 Tr., p. 176:4-6.) Nor does Gaya allege that anyone at Gaya showed the datebook to Applied. Also, no Gaya witnesses testified that he ever used the term "flubber" with anyone from Applied. That both Gaya and Applied used the same term to describe the gel material is a coincidence that leads nowhere.

127. In sum, there is nothing to corroborate the testimony of Bermingham and Rosney that any future HALS design concepts were discussed with Taylor and Johnson during their March 2000 visit to Applied. Apart from the testimony of Bermingham and Rosney, all evidence is to the contrary. Thus, Gaya has failed to

meet its burden of showing a communication of what it contends to be a conception of or contribution to the conception of the invention claimed in the Applied Patents during the March 2000 meeting.

128. Even if the Court draws the best possible inferences from the allegedly similar drawings and the "flubber" coincidence, along with the testimony of Bermingham and Rosney, the showing does not rise to the level of clear and convincing proof that disclosures were made in March 2000.

129. Applied asserts that because no communications of future HALS design concepts occurred during the March 2000 meeting in Ireland, and because Applied conceived of and reduced to practice the inventions claimed in the Applied Patents before any August communications from Gaya, discussed supra, the Court need go no further to conclude that no one from Gaya is a sole or joint inventor of the Applied Patents.[6] Nonetheless, the Court considers the differences between the inventions claimed in the Applied Patents and the Gaya concepts and whether those concepts were already known in the art.

2. The Design Proposals Sent To Scott Taylor In August 2000 Are Not A Contribution To Any Claim Of The Applied Patents.

[6]However, to be explicit, the Court's finding of no disclosures prior to Applied's conception is sufficient to support the Court's overall factual finding that the Gaya personnel were neither sole nor joint inventors.

130. The materials sent to Taylor by Bermingham in late August included two design proposals: an Intromit sleeve attached to a wound retractor and a twist valve attached to a wound retractor. (Taylor, ¶¶ 53-58; Ex. 197 at CV11-1406AM0067714, CV11-1406AM0067721; see also Ex. 337 (showing materials were delivered to Applied on August 28, 2000).) The materials sent by Bermingham also included two prototypes that corresponded to the described proposal of an Intromit sleeve attached to a wound retractor. (Taylor, ¶¶ 57-58.)

131. By August 28, 2000, when the design proposals were received by Taylor, Applied's development work leading to the GelPort® product was almost complete. (See generally, Brustad, Ewers, Dulak.) As described, supra, the inventions had been conceived and prototypes had been created by that date.

132. Additionally, combining a wound retractor and an Intromit or combining a wound retractor and a twist valve is not the invention claimed in the Applied Patents or any contribution thereto. Additionally, as described in more detail infra, these designs do not evidence any contribution to the inventions claimed in the Applied Patents. (See Sheehan, ¶¶ 96-116.) As also described in more detail infra, attaching a valve to wound retractors was known and twist or iris valves were also known. Sharing these concepts with Applied would have amounted to only explaining the state of the art.

D. Gaya Failed To Prove Any Collaboration With The Inventors Named

On The Applied Patents.

133. The disclosures of new HALS concepts that Gaya alleges to have made at the March 2000 meeting were purportedly made to Taylor and Johnson. But Taylor and Johnson were not involved in the development of the inventions claimed in the Applied Patents. (Taylor, ¶ 44; Johnson, ¶¶ 5-6.) No evidence suggests that any of the inventors named on the Applied Patents used any information allegedly provided by Gaya.

134. By the time Bermingham sent the two design proposals in late August, the conception of the claimed inventions had been completed. (See generally Brustad , Ewers, Dulak.) No evidence suggests that any of the inventors named on the Applied Patents used the information sent by Bermingham in connection with the conception of the claimed inventions. Also Brustad, Dulak, and Ewers all testified that nothing from Gaya contributed to the inventions claimed in the Applied Patents. (Brustad, ¶ 86; Dulak, ¶ 4; Ewers, ¶ 6.)

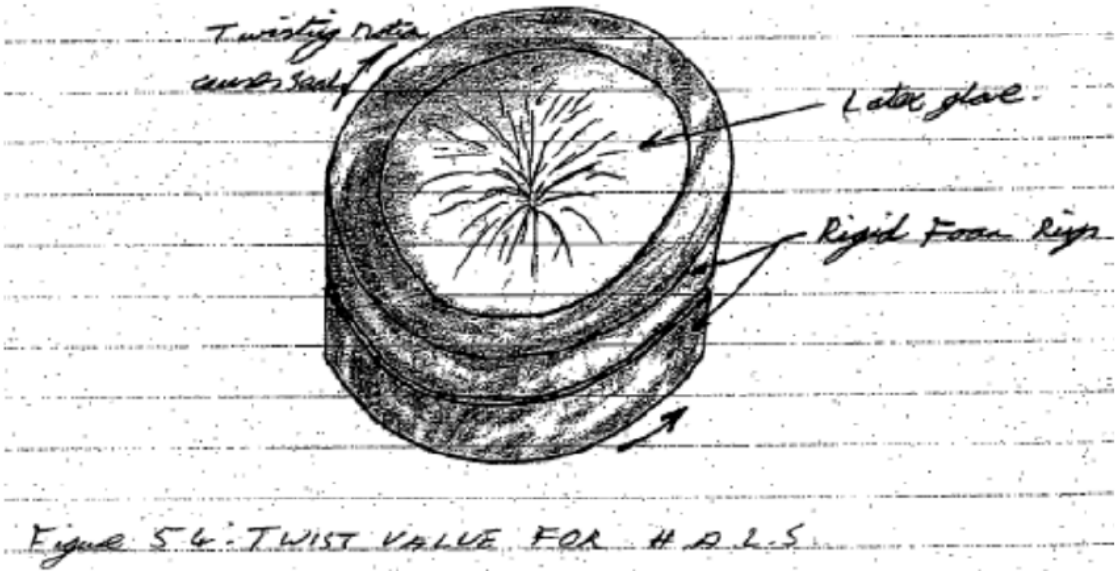
135. Ewers testified that Taylor and Johnson had communicated nothing from their contacts with Gaya, and that he personally had no contacts with Gaya personnel. (Day 2 Tr., p. 133:4-14.) The Court found him credible.

E. Gaya Designs Did Not Amount To A Contribution To The Inventions Claimed In The Applied Patent.

136. Next, the Court considers the design elements which Gaya contends amount to a contribution to Applied's inventions. By and large, they can all be found in the existing art, and thus without more are not contributions for inventorship purposes. Moreover, some of the design elements were disclosed in Irish Short Term Application No. IE990218. The Application is listed as one of the References Cited on the face of the Applied Patents, was therefore considered by the Patent Office during examination, and the issued claims were found to be patentable over this disclosure.

1. Twist Valve Designs.

137. As evidence of an alleged conception of the inventions claimed in the Applied Patents, Gaya relies on a number of twist valve or iris-type designs found in the Gaya notebooks and in a document sent to Taylor from Bermingham in August 2000. (Ex. 154 at CV11-1406AM0159276-77 and CV11-1406AM0159294-95; Ex. 156 at CV11-1406AM0159361-62; Ex. 197 at CV11-1406AM0067722.) An example of a twist valve design from one of Gaya's notebooks is shown below.



(Ex. 154 at CV11-1406AM0159276-77.)

138. The twist valve design is described in one Gaya notebook as being "made from two circular pieces of rigid foam, one latex glove, and adhesive tape. . . . The latex glove was inverted over the top and bottom foam rings and was held in place with tape. The two rings were twisted in opposite directions, thereby twisting the latex and causing the required seal . . . ." (Id.)

139. The Applied Patents do not describe or claim twist valves. (Exs. 1, 8, 40, 667, 729.) As explained in more detail infra, any disclosure by Gaya to Applied of twist valve designs is not evidence of any contribution to the inventions claimed in the Applied Patents.

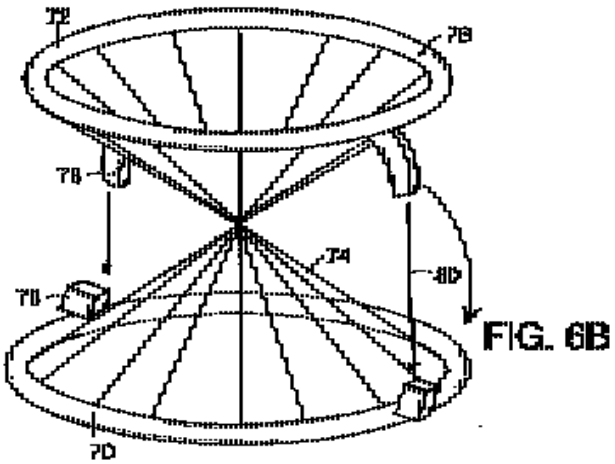
140. Gaya witnesses described twist valves described in a manner suggesting similarities with Applied's claimed inventions. (See, e.g., Bermingham, ¶ 52 (characterizing twist valves as something that "could be made from different types of self-sealing materials, such as gel or jelly, foam, or any other type of polymer that allowed for self-sealing"); Caldwell, ¶ 31 (similar). These characterizations are not corroborated and, in any event, were not the claimed inventions of the Applied Patents. Gaya exert Dr. John M. Collins, Ph.D. ("Collins") conceded that the twist valve reflected in Bermingham and Rosney's work was not associated with an encapsulated gel material, as is the case in the Applied Patents. (Day 2 Tr., pp. 33:21-34:2, 47:3-19.)

141. Iris or twist valves for use in hand access devices were also well known in the art by 2000, as evidenced by the Hakko LapDisc product (Exs. 935-936), U.S. Patent No. 5,906,577 to Beane ("the Beane '577 patent") that issued on May 25, 1999 (Ex. 762), and U.S. Patent No. 5,640,977 to Leahy ("the Leahy '977 patent") that issued on June 24, 1997 (Ex. 748).

142. The Hakko LapDisc was a commercially available product by at least late 1999 or early 2000. (Brustad, ¶ 13; Exs. 935, 936.) The LapDisc product includes a wound retractor that includes a stretchable elastomeric tubular sleeve positioned between an upper ring and a lower ring. (Exs. 935, 936; see also Sheehan, ¶ 44.) An adjustable twist valve is attached above the wound retractor and includes two rings joined by a flexible material. (Id.) A photo of the twist

valve of the LapDisc product in a closed position is shown below.

143. The Beane '577 patent also describes the use of an iris or twist valve with a HALS device, including the use of a twist valve that can be removably attached to a wound retractor. (Ex. 762, col. 9, lines 26-42 and Fig. 6B). Figure 6B from the Beane '577 patent, which illustrates the twist valve, is shown below.



The patent also discloses using latex for the skirts, collars, and sleeves of the

different described embodiments. (Id., col. 13, lines 22-26.)

144. The Leahy '977 patent describes a wound retractor and an external hand seal. (See, e.g., Ex. 748 at Fig. 3.) A sleeve can connect to the wound retractor with a first sealing means to seal an opening at the distal end of the sleeve. (Id., col. 3, lines 23-47.) The sealing means can be a twist valve that includes two rings joined by a tubular sealing member of a flexible material to form an iris seal. (Id., col. 6, lines 41-47 and Figs. 16A-16C.) Figures 16A-16C from the Leahy '977 patent, which illustrate the twist valve, are shown below.

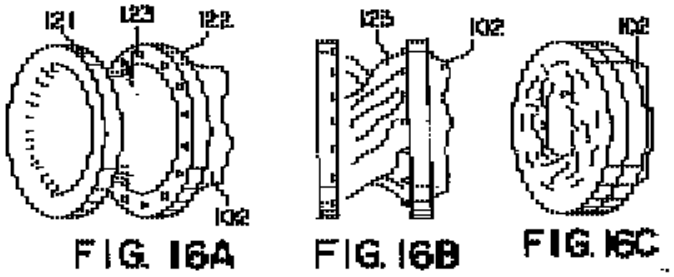


FIG. 16A FIG. 16B FIG. 16C

145. There is no record that Gaya ever pursued patent protection on the concept of an iris or twist valve, either by itself or coupled to a wound retractor. Caldwell testified that he was not aware of any Gaya patents or patent applications that were filed showing any of Gaya's twist valve concepts. (Day 2 Tr., p. 12:19-21; see also Day 1 Tr., pp. 223:15-225:7.) Particularly as a patent holding company Gaya had an incentive to file patent applications if it believed the twist valve concept to be inventive. The Secrecy Agreement stated that any liability on

the part of Applied for using information provided by Gaya under the Secrecy Agreement after four years would be limited to a claim for patent infringement of any patents Gaya may obtain. (Ex. 4 at p. 2, ¶ 4; Day 1 Tr., pp. 222:19-223:14.) Thus Gaya could have been expected to perfect its rights under the Secrecy Agreement by securing patents on an inventive matter it held. That Gaya did not file any patent applications for the twist valve design further illustrates the design was in the prior art (or at least in Gaya's view did not merit a patent application), and is not any evidence of a contribution to the conception of Applied's claimed inventions.

146. Any communication of twist valves by Gaya to Applied would have merely conveyed the state of the prior art.

147. The Beane '577 patent and the Leahy '977 patent are both on the list of References Cited on the face of each of the Applied Patents and were therefore considered by the Patent Office during examination. (Exs. 1, 8, 40, 667, 729.) The fact that the Patent Office granted the Applied Patents over the Beane '577 patent and the Leahy '977 patent also illustrates the difference between the inventions claimed in the Applied Patents and iris or twist valve designs.

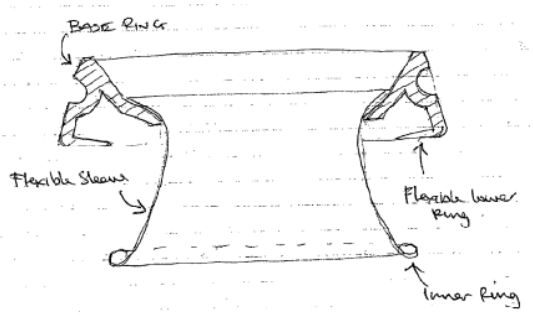
148. Gaya contends that because its twist valve was not adjustable it was different from, for example, the LapDisc product. (Day 1 Tr., p. 122:4-15.) But this misses the point because a twist valve such as the LapDisc that can have an

open position in addition to a closed position, thus showing that twist valves in closed positions were known. Further, Gaya's twist valves used only latex as the connecting sleeve (see Ex. 154 at CV11-1406AM0159276-77), and the use of latex with twist valves was known by at least the Beane '577 patent. (Day 3 Tr., pp. 145:22-146:1.)

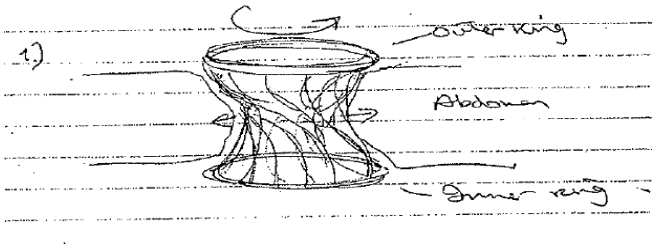
149. Gaya's expert Dr. John Collins Ph.D. ("Collins") made no comparison of the Gaya twist valve with the prior art. (Day 2 Tr., p. 31:3-17.)

2. Retractor And Retractor With Valve Designs.

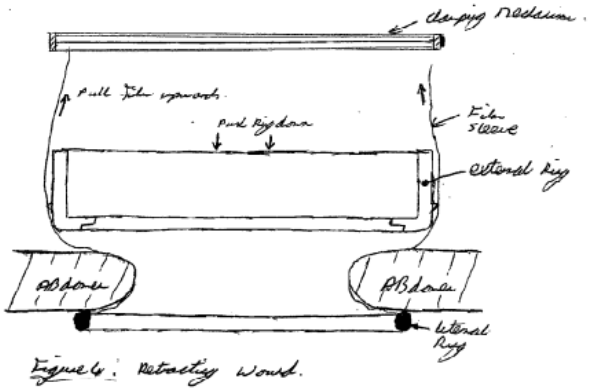
150. As evidence of conception of the inventions claimed in the Applied Patents, Gaya also relies on a number of wound retractor designs described or depicted in Gaya documents. (See, e.g., Ex. 156 at CV11-1406AM0159375-76, CV11-1406AM0159361-62, CV11-1406AM0159364-65, CV11-1406AM0159369-70; Ex. 197 at CV11-1406AM0067715-18.) These retractors consist generally of an internal ring, an external ring, and a material extending between the internal and external rings. Examples of some of the wound retractor designs relied upon by Gaya are shown below.

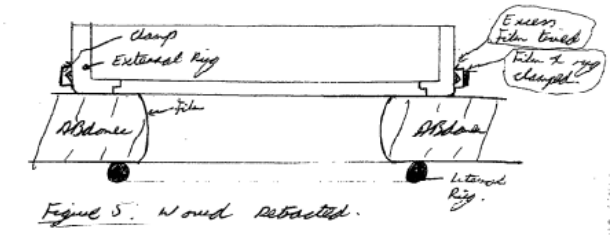


(Ex. 156 at CV11-1406AM0159375.)

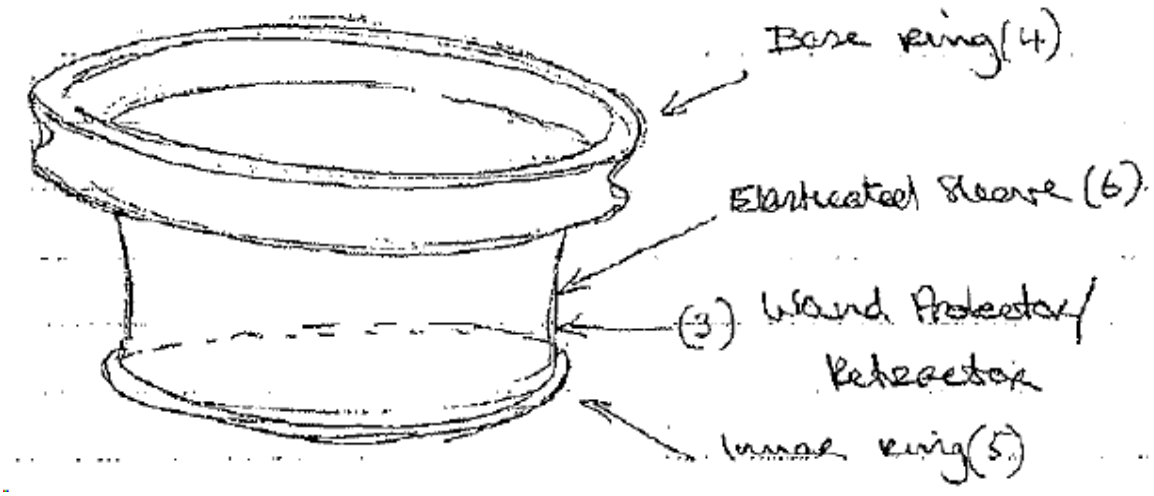


(Id..at CV11-1406AM0159361-62.)





(Id. at CV11-1406AM0159364-65.)



(Id. at CV11-1406AM0159369-70.)

151. Wound retractors with an internal ring, an external ring, and a connecting sleeve were known in the art, such as the Dexterity Protractor (Ex. 951); the retractors associated with the Smith and Nephew HandPort product (Ex. 784) and the LapDisc product (Ex. 935); the retractors in the Beane '577 patent (Ex. 762); the retractors described in U.S. Patent No. 5,514,133 to Golub ("the Golub '133 patent") that issued on May 7, 1996 (Ex. 745); the retractor described in U.S. Patent No. 3,347,226 to Harrower ("the Harrower '226 patent") (Ex. 994) that issued on October 17, 1967; and the retractors described in the Leahy '977 patent (Ex. 748).

152. Dexterity's Protractor product was available on the market by at least 1999. (Brustad, ¶¶ 22-24; Exs. 951, 952.) The Protractor is an adjustable wound retractor with an upper rotatable ring connected to a lower ring by a tubular

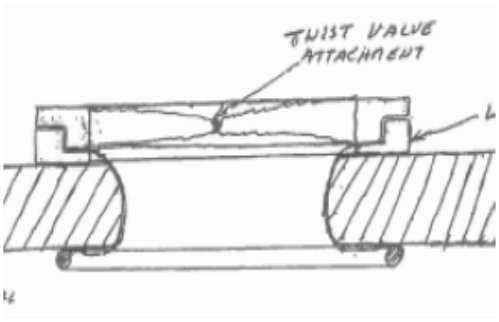
elastomeric sleeve. (Id.) The lower ring is placed in the patient's abdomen through an incision and the upper ring is rolled down to create tension and seat the upper ring on the abdomen. (Id.) A picture of Dexterity's Protractor product is shown below.

153. The Smith and Nephew HandPort product was commercially available by at least late 1999. (Brustad, ¶¶ 29-30; Exs. 784, 785.) The HandPort product includes an adjustable wound retractor with an elastomeric sleeve extending between an inflatable upper ring and a flexible lower ring for insertion through an incision into a patient's abdomen. (Id.) A sleeve for a surgeon's arm detachably couples directly to the upper ring, allowing the surgeon to insert his or her hand through the retractor and into the abdomen. (Id.) A photo of the wound retractor of the HandPort product is shown below.

154. The LapDisc product includes a wound retractor that includes a stretchable elastomeric tubular sleeve positioned between an upper ring and a lower ring. (Exs. 935, 936; see also Sheehan, ¶ 44.) In use, the lower ring of the retractor is placed in an incision and seated against the interior abdominal wall. (Sheehan, ¶¶ 44-45.) This allows the flexible sleeve to stretch to retract the wound and also allows the wound retractor to adjustably fit abdomens of different sizes. (Id.)

155. A comparison of a photo of the LapDisc product to one of the wound retractor designs relied upon by Gaya, which is shown in the Gaya document as being attached to a twist valve, is shown below.

Ex. 935 (Hakko LapDisc)



Ex. 197 at CV11-1406AM0067722

156. The Beane '577 patent describes a wound retractor having an inner ring for insertion through an abdominal incision, outer collars, and a skirt that can join the inner ring and outer collars. (Ex. 762 at col. 6, lines 7-44.) If the inner ring is larger than an incision, it can be deformed for insertion through the incision. (Id., col. 6, lines 16-19.) The collars can be inflatable, and as they are inflated they draw the skirt upward to press the inner ring against the surface of the abdominal wall and they draw the skirt radially outward to draw the skirt tightly against the edges of the incision to produce a gas-tight seal. (Id., col. 6, lines 28-44.)

157. The Beane '577 patent further describes that a seal through which a surgeon's hand can be inserted, including an iris or twist seal, can be detachably connected to the base ring of the wound retractor. (Id., col. 5, lines 29-40, col. 7, lines 37-45, col. 9, lines 7-42, and Figs. 4, 6A, and 6B.) Figure 5 from the patent, illustrating how a seal can be coupled to the wound retractor, is shown below.

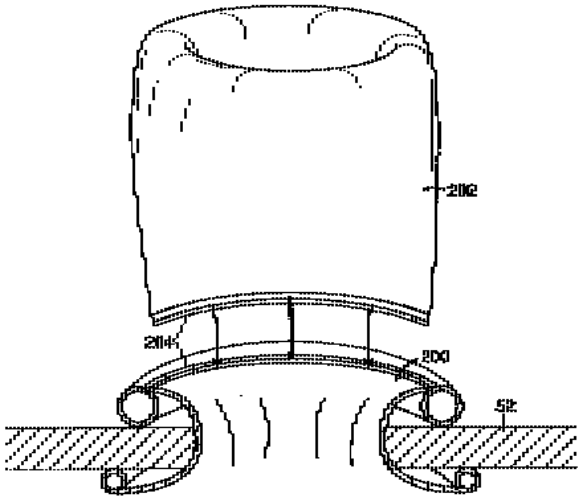


FIG. 5

158. The Beane '577 patent also describes that a low-profile snap cap can be attached to the wound retractor. (Id., col. 10, lines 1-49.) Instruments can then be inserted through openings in the cap. (Id.) Figure 8 from the patent, illustrating how the cap can be coupled to the wound retractor, is shown below.

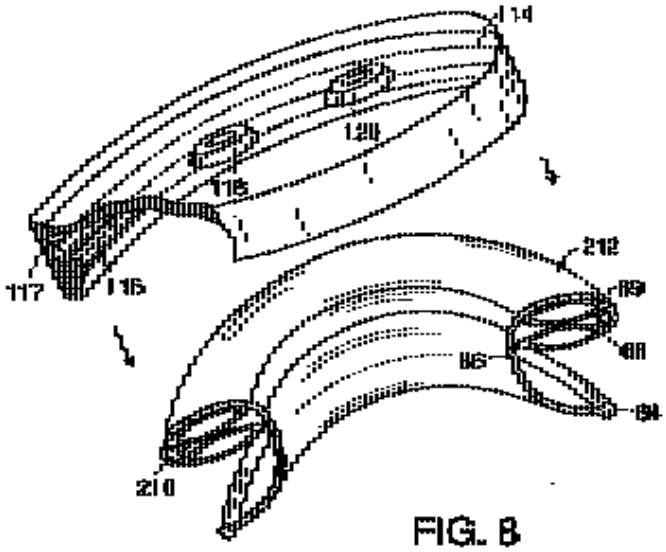
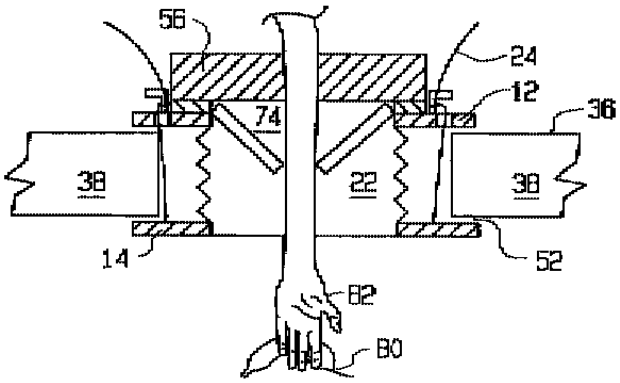


FIG. 8

159. The Golub '133 patent describes an adjustable hand access device with a proximal seal. (Ex. 745 at Fig. 1.) The device includes a first plate that engages an outer surface of the abdominal wall and a second plate that engages an inner surface of the abdominal wall. (Id., col. 4, lines 17-32.) A flexible sleeve extends between the plates and is expandable and contractible longitudinally. (Id., col. 4, lines 36-39.) A seal member can be mounted to the first plate. (Id., col. 4, lines 55-57.) Figure 5 from the patent, which illustrates one embodiment of the device positioned within an incision, is shown below.



160. The Harrower '226 patent (Ex. 994) describes a double-ring wound retractor such as depicted in Figure 2 of the patent, shown below.

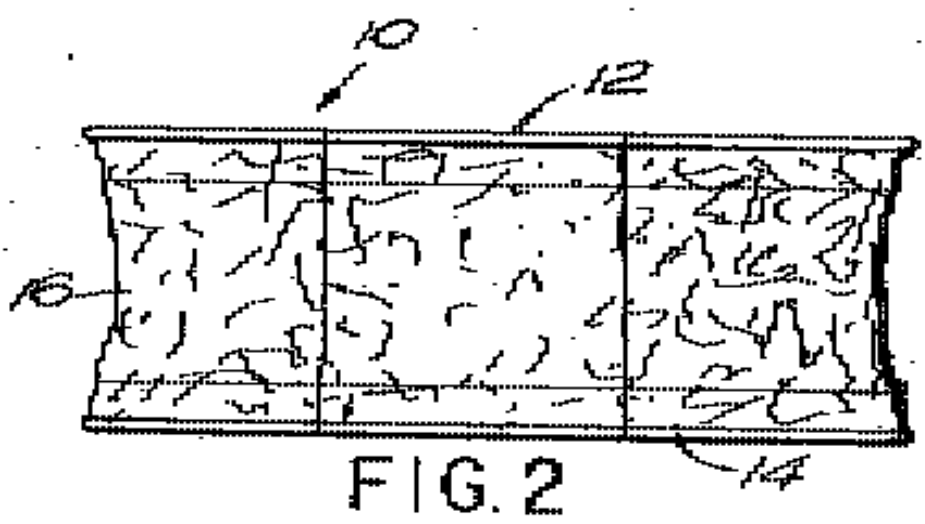


FIG. 2

To be inserted through an incision, the longitudinal side portions of an inner ring 14 are pressed together. (Ex. 994, col. 3, lines 7-10.) The ring is then inserted into the wound and allowed to expand to its normal form, at which point it can be positioned on the inside of the peritoneum. (Id., col. 3, lines 10-13.)

161. The Leahy '977 patent describes a wound retractor and an external hand seal. (See, e.g., Ex. 748 at Fig. 3.) The wound retractor comprises a thin flexible tube 13 and flexible rings 14, 16 at opposite ends thereof. (Id., col. 4, lines 4-6.) Figure 3 from the patent, which shows the wound retractor attached to an external seal, is shown below, with labels added to identify the rings 14, 16, wound protector 12, and sleeve 18.

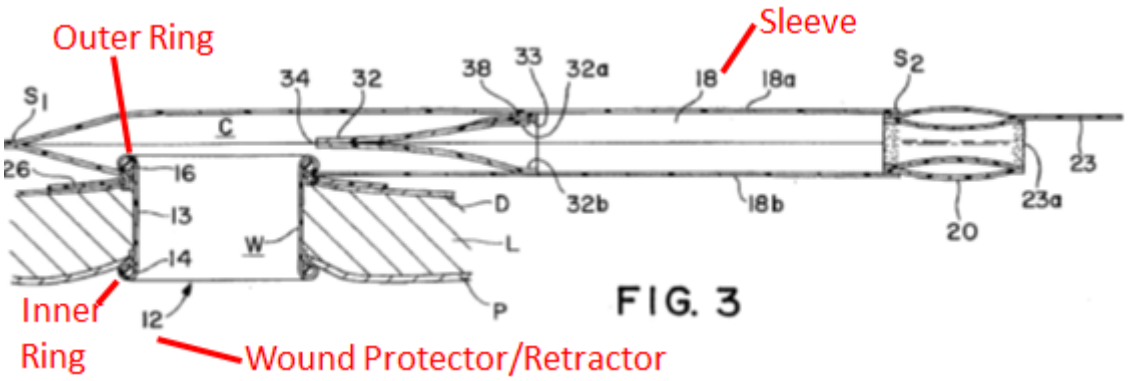


FIG. 3

162. U.S. Patent No. 5,741,298 to MacLeod ("the MacLeod '298 patent"), which issued on April 21, 1998, is another example of a wound retractor to which a sealing cap can be removably coupled. (Ex. 352 at Fig. 3.) The sealing ring is a low profile device used to seal an incision into a patient's body cavity. (Id., col. 4, line 60 to col. 5, line 1.) Figure 2 from the MacLeod '298 patent, which depicts the cap attached to the wound retractor, is shown below, with labels added to identify the removable cap and wound retractor.

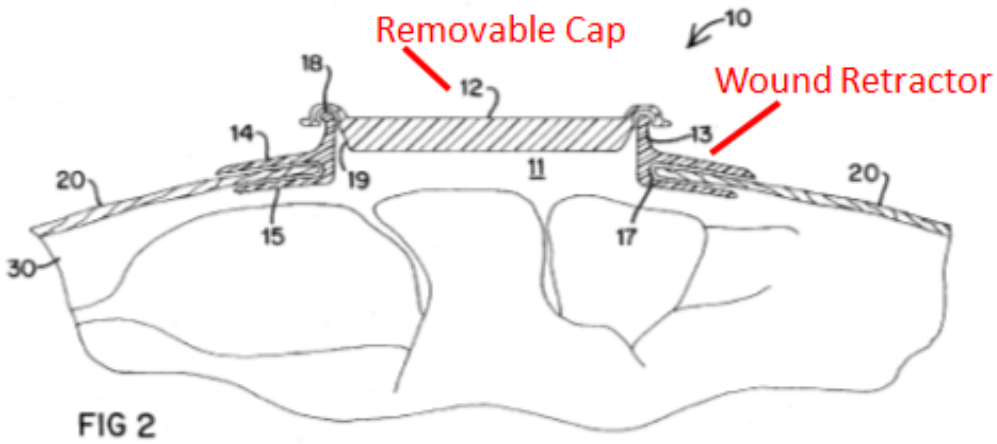
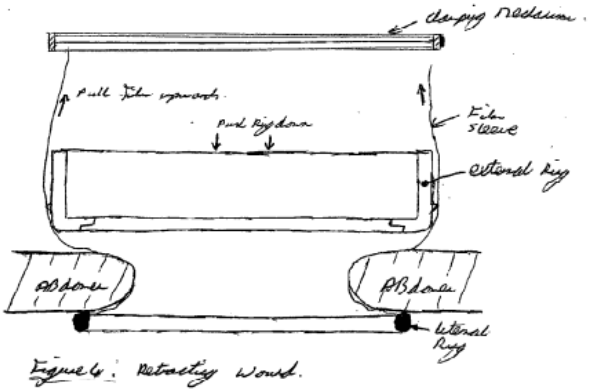


FIG 2

163. The sealing cap can include a cap port through which instruments can

be inserted and which can seal against the instruments. (Id., col. 8, line 64 to col. 9, line 7 and Fig. 4.) The sealing cap can be removed as desired from the sealing ring, such as to allow for easy removal of portions of the contents of the body cavity. (Id., col. 7, lines 37-44 and Fig. 3.)

164. One of the retractors that Gaya relies upon is described as consisting of an internal ring, a film sleeve, an external ring, described by Bermingham as "not permanently attached" to the sleeve, and a clamping mechanism, used to close and seal the sleeve against the external ring. (Bermingham, ¶ 20; see also Ex. 156 at CV11-1406AM0159364-65.) Images of this wound retractor design are shown below.



(Ex. 156 at CV11-1406AM0159364-65.)

165. Wound retractors with sleeves or membranes that are attached to an inner ring and then pulled to retract a wound and clamped in place to a non-permanently attached outer ring were already known in the art. Such retractors included at least retractors described in the Kaji '426 patent. (Ex. 357 at col. 7, lines 33-56 and Figs. 4A and 4B.)

166. The Kaji '426 patent describes an adjustable wound retractor that can be used for abdominal walls of different thickness. (Id., Figs. 4A and 4B.) The wound retractor includes an internal ring that connects to a sleeve. (Id., col. 7, lines 33-44 and Fig. 3.) The sleeve can be pulled through an incision to accommodate the thickness of the abdominal wall and attached to a sleeve fixing member. (Id., col. 7, lines 33-56.) In some embodiments, this can be done by pulling the sleeve around a flange. (Id.)

167. An instrument valve is also attached to the sleeve fixing member. (Id., col. 6, lines 29-33.) The instrument valve can include a small hole that can expand and seal against a surgeon's hand. (Id., col. 6, lines 23-29, 55-65 and Fig. 1.)

168. The images reproduced below from the Kaji '426 patent and the Gaya wound retractor design show the similarities in the designs.

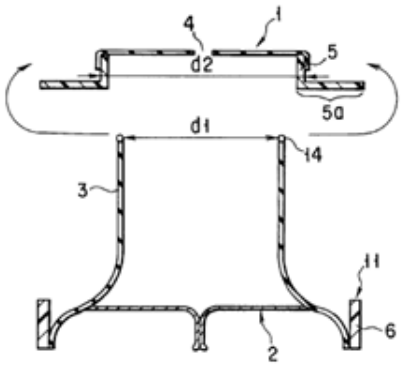
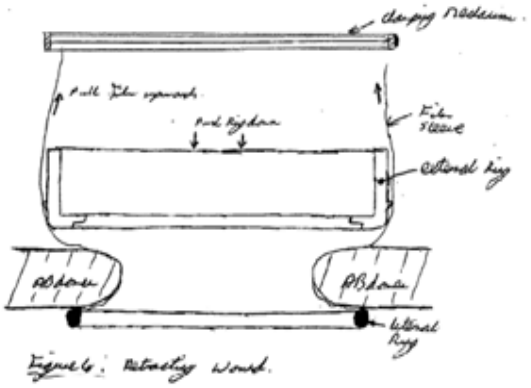


Fig. 3

Kaji '426 Patent (Ex. 357)



Ex. 156 at CV11-1406AM0159365

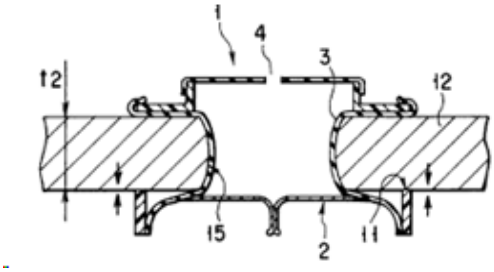
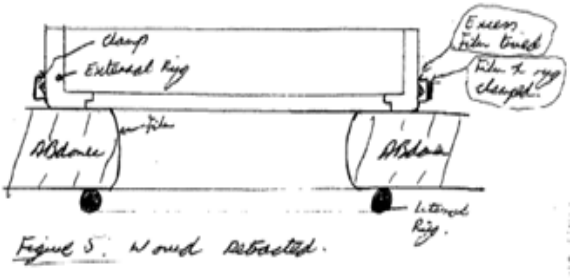


Fig. 4B

Kaji '426 Patent (Ex. 357)



Ex. 156 at CV11-1406AM0159365

169. Any communication of wound retractor designs by Gaya to Applied would have merely conveyed the state of the prior art.

170. Those claims of the Applied Patents that refer to a wound retractor or associated structure also claim a specific associated gel valve. (Ex. 40 ('221 patent) at Claims 1-23 and Ex. 667 ('234 patent) at Claims 1, 10-13 and 24-25.) None of the wound retractor designs relied upon by Gaya include a gel seal coupled to the wound retractor. As explained further, infra, any communication by Gaya to

Applied of the wound retractor designs relied upon by Gaya could not be evidence of any contribution to the inventions claimed in the Applied Patents. The proposals sent by Gaya to Applied in late August 2000 actually pictured a twist valve combined with a commercially available Smith and Nephew HandPort wound retractor. (Ex. 197 at Figs. 10 and 11; Day 1 Tr., p. 88:10-17.)

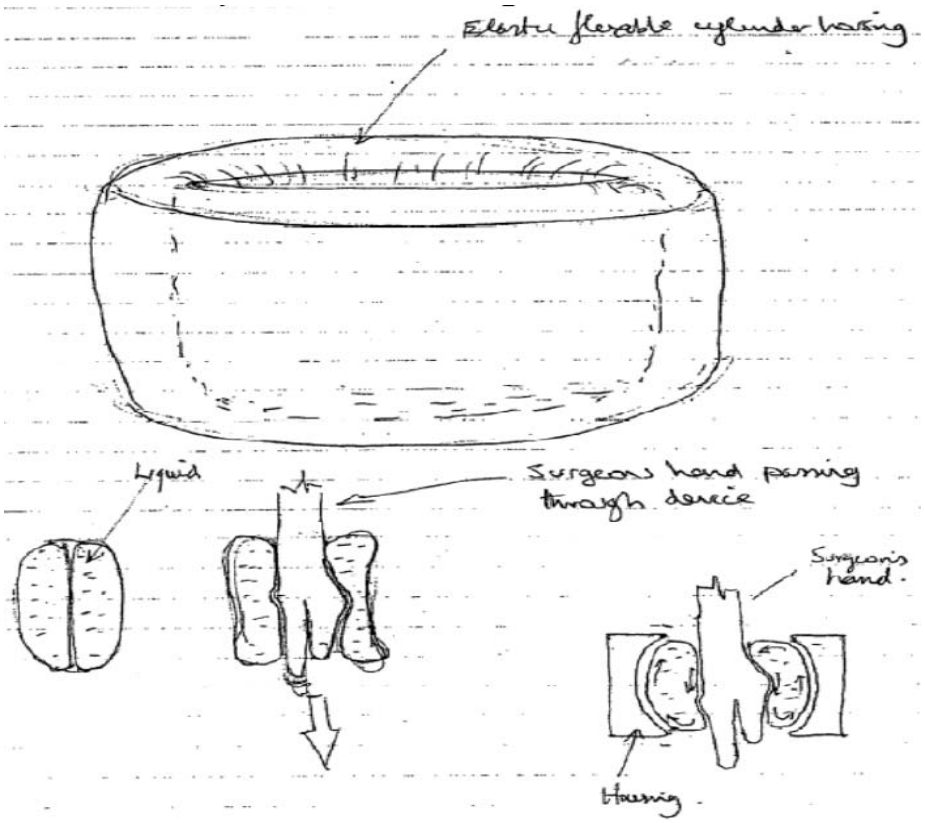
171. Some of the wound retractor designs relied upon by Gaya, including retractor designs that include an outer base ring, an inner ring, and a sleeve extending between the two rings, and to which a valve structure can be attached, are described in Gaya's Irish Short Term Application IE990660. (Ex. 675 at Figs. 2 and 3.) The Irish Short Term application is listed as one of the References Cited on the face of the Applied Patents and was therefore considered by the Patent Office during examination. (Exs. 1, 8, 40, 667, 729.) The fact that the Patent Office granted the Applied Patents over Gaya's Irish Short Term Application IE990660 illustrates the difference between the inventions claimed in the Applied Patents and the wound retractor designs relied upon by Gaya.

172. Gaya's expert Collins made no comparison of the Gaya wound retractor with the prior art. (Day 2 Tr., pp. 31:18-32:13.)

3. Liquid-Filled Bladder.

173. As evidence of conception of the inventions claimed in the Applied

Patents, Gaya also relies upon a liquid-filled bladder design depicted in a Gaya notebook. (See, e.g., Collins, Appendix A at 3-4, 14-15, 23-24, 35-36, 39-40, and 60; Appendix B at 3-4, 15-16, 19-20, 34-35, and 41-42; Appendix C at 1-2, 6-7, 10-11, 15-16, 22-23, 28-29, 34-35, 39-40, 43-44, 47-48, and 51-52; Appendix D at 5-6, 11-12, 13, 18-19, 26-27, 32-33, 39-42; Appendix E at 3-5,10, 12-13, 15-16, 21-22, 29, and 35-36.) Images of the design from the notebook are shown below.



(Ex. 154 at CV11-1406AM0159289-90.)

174. The notebook describes this design as including a cylindrical shaped

device with a central lumen that is normally closed. (Id.) The cylinder is described as made from a highly elastic rubber material that is filled with a liquid, such as water, oil, or gel. (Id.) The liquid gel material was intended to be something with a viscosity a bit higher than water. (Day 1 Tr., p. 178:6-11.)

175. The notebook further describes that the device is to be attached to the patient over the incision. (Ex. 154 at CV11-1406AM0159290.) The notebook states that the device would normally be attached to a wound retractor. (Id.) However, the notebook provides no explanation as to how the device could attach to a patient or a wound retractor. (Id.; see also Sheehan, ¶ 119.)

176. The notebook also describes a configuration in which the device is held within a semi-rigid housing. (Ex. 154 at CV11-1406AM0159290.) The notebook describes that as a hand is inserted though the device, the housing will constantly invert on itself. (Id.) The notebook provides no explanation as to how the device could remain in place as it rotates within a housing. (Id.; see also Sheehan, ¶ 119.)

177. There is insufficient information provided to reduce these concepts to practice. (Sheehan, ¶ 120.) Further, Cummins never tried to make prototypes as shown on these pages while at Gaya. (Day 1 Tr., p. 179:7-10.)

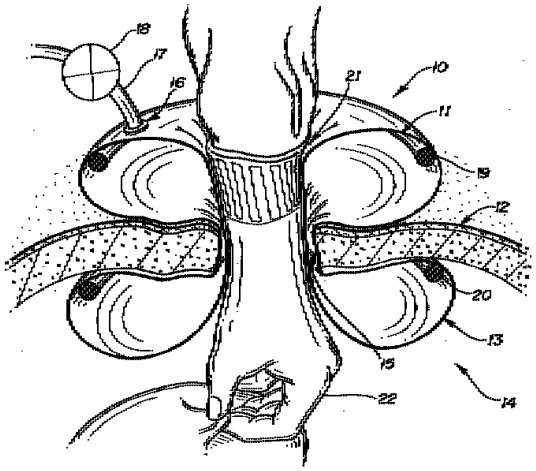
178. As of March 2000 when this liquid-filled bladder design was alleged to

have been communicated by Gaya to Applied, Applied had already discussed the same concept that had been suggested to Applied by Dr. Clayman during a meeting in December 1999. (Brustad, ¶ 10; Ex. 988.) Applied did not ultimately pursue the design because Applied realized that it would not work. (Brustad, ¶ 10.)

179. Any communication by Gaya to Applied of the liquid-filled bladder design, which was non-functional and which Applied already knew about, could not be evidence of any contribution to the inventions claimed in the Applied Patents.

180. Additionally, the general idea of using a casing or bladder to attempt to form a seal was already known in the art. For example, U.S. Patent No. 5,366,478 to Brinkerhoff ("the Brinkerhoff '478 patent"), which issued on November 22, 1994, describes a self-sealing hand access device that can be inserted through an incision in a patient's abdomen. (Ex. 344.) The patent describes a "first inflatable toroidal section 11 for positioning outside of the abdominal wall 12, a second toroidal section 13 for positioning inside the body cavity 14 and a transition section 15, which communicates with the first and second inflatable toroidal sections." (Id., col. 4, lines 16-20.) Instruments or a surgeon's hand can be inserted through the central opening of the device, which "conforms to the shape of the instrument or hand passed through it to maintain an adequate seal." (Id. at abstract.) Figure 3 from the Brinkerhoff '478 patent is shown below.

FIG-3



181. The use of sealing bladders that can be attached to wound retractors was also known, as evidenced by at least the Beane '577 patent. (Ex. 762 at col. 9, lines 7-14.)

182. A liquid-filled bladder is also shown in Gaya's Irish Short Term Application IE990218. (Ex. 760.) A figure from that application is shown below.

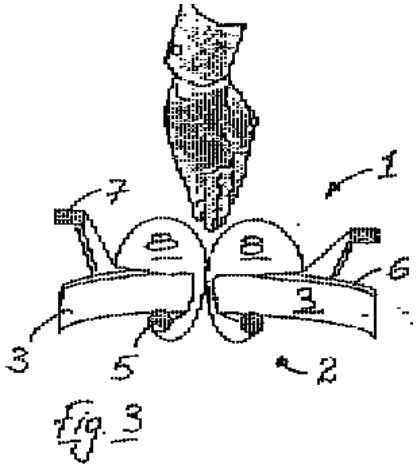


fig. 3

The patent application describes that the bladder is filled with a viscous or semi-

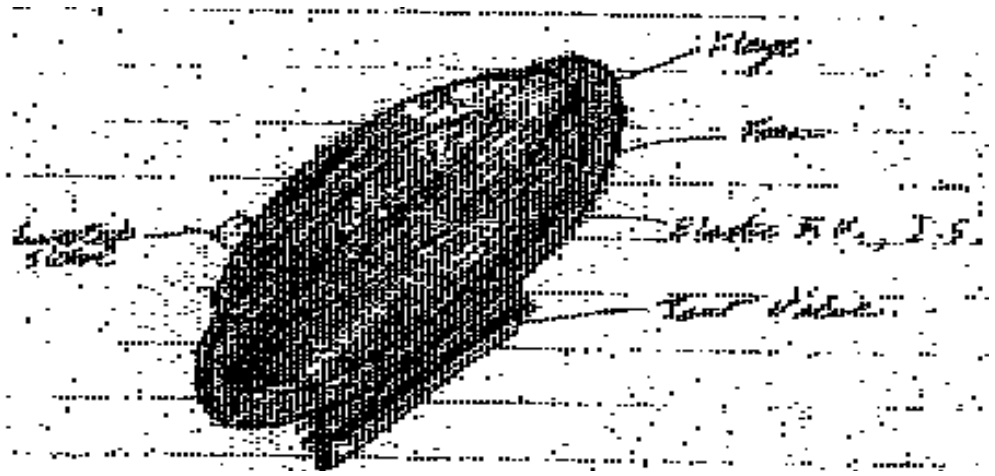
viscous liquid, such as saline, gel, or foam. (Id. at CV11-1406AM0067011.)

183. The Irish Short Term Application IE990218 is listed as one of the References Cited on the face of the Applied Patents, was therefore considered by the Patent Office during examination, and the issued claims were found to be patentable over this disclosure. (Exs. 1, 8, 40, 667, 729.) The fact that the Patent Office granted the Applied Patents over Gaya's Irish Short Term Application IE990218 illustrates the difference between the inventions claimed in the Applied Patents and the liquid-filled bladder designs relied upon by Gaya.

184. As explained further, infra, the inventions claimed in the Applied Patents are all substantially different from the liquid-filled bladder designs relied upon by Gaya, and any communication by Gaya to Applied of such designs could not be evidence of any contribution to the inventions claimed in the Applied Patents. For example, Collins conceded that the Gaya liquid-filled bladder had no flanges. (Day 2 Tr., p. 62:4-10.)

4. Incorporating Foam Into Gaya's Intromit Product.

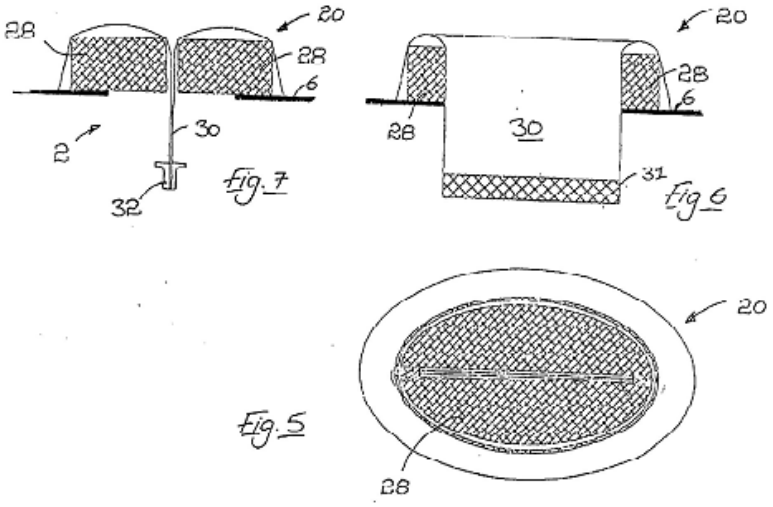
185. As evidence of conception of the inventions claimed in the Applied Patents, Gaya also identifies and relies upon a variety of foam-based designs found in Gaya notebooks. One example is the design reproduced below.



(Ex. 154 at CV11-1406AM0159244-45; see also id. at CV11-1406AM0159247 (showing similar design but with adhesive flange removed).)

186. These foam designs are like the Intromit but with foam instead of the inflatable chamber. (Day 2 Tr., p. 57:10-13.) The design includes an elastic feather valve, a sleeve passing through the incision to an internal taut valve, and a flange. (Ex. 154 at CV11-1406AM0159244-45.)

187. These foam designs are similar to those shown in Irish Short Term Application No. IE990218, reproduced below.



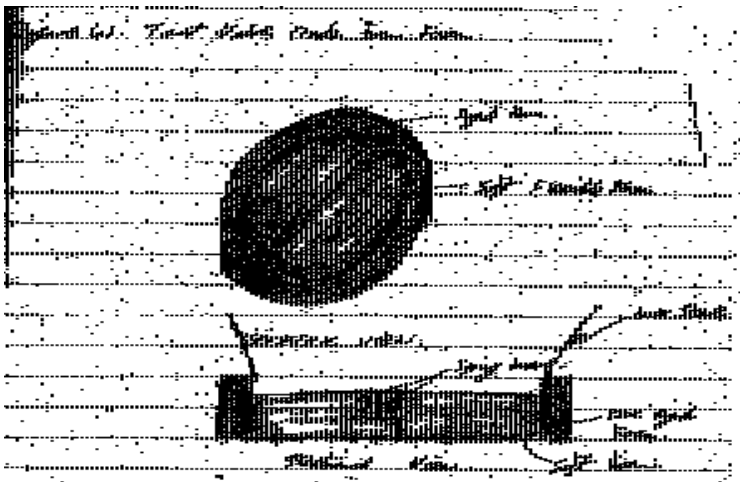
(Ex. 760 at CV11-1406AM0067020.)

188. The design described in Irish Short Term Application No. IE990218 includes a foam shell with parts that can move relative to each other to allow a surgeon access to a body cavity. (Id. at CV11-1406AM0067015.) A sleeve covers the shell and passes into the cavity where it is attached to a distal valve with a mechanical seal. (Id.) The foam is described as being able to mold to an inserted instrument to prevent loss of pressure. (Id.)

189. As discussed supra, Irish Short Term Application No. IE990218 is listed as one of the References Cited on the face of the Applied Patents, was therefore considered by the Patent Office during examination, and the issued claims were found to be patentable over this disclosure. (Exs. 1, 8, 40, 667, 729.) The fact that the Patent Office granted the Applied Patents over Gaya's Irish Short Term Application IE990218 illustrates the difference between the inventions claimed in

the Applied Patents and the foam based designs relied upon by Gaya.

190. Gaya also relies on the valve design reproduced below.



(Ex. 154 at CV11-1406AM0159248.) The sketch is titled "Taut Valve Made From Foam." (Id.)

191. The taut valve includes a rigid, outer foam ring and a soft, flexible inner foam. (Id.) Springs through the center of the foam were expected to cause the foam to open and close upon hand insertion and removal. (Id.) The notebook describes the outer ring as being flexible enough to allow the taut valve to pass through an incision but rigid enough to anchor the device. (Id.) Thus, the notebook describes this taut valve as being used only as an interior valve, as further evidenced by the sleeve shown extending upward from the valve. (Id.)

192. The valve would not form a seal with an instrument, such as a hand,

inserted through the foam. (Sheehan, ¶ 134.) The failure to seal would be exacerbated with movement of the instrument. (Id.) Any communication by Gaya to Applied of this valve design, which would not even seal with an instrument or hand, could not have contributed anything to the inventions claimed in the Applied Patents.

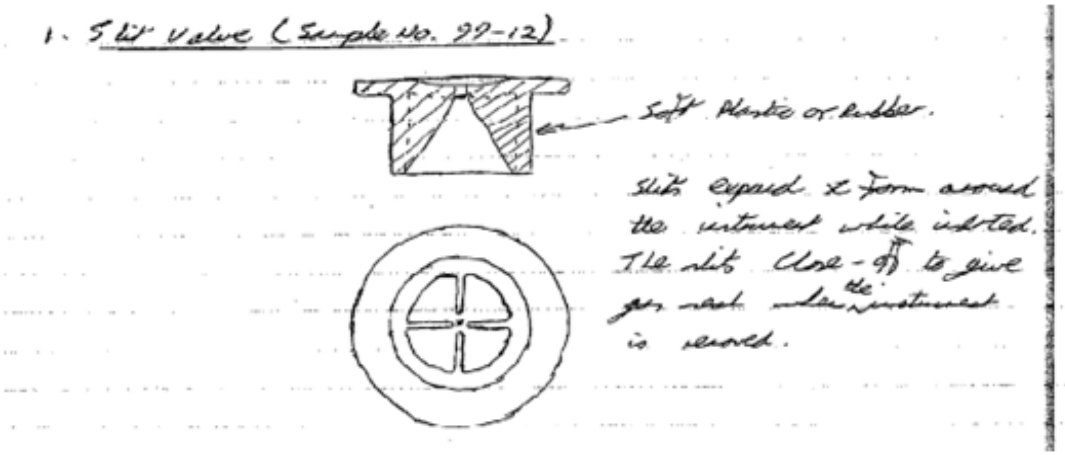
193. Gaya witness Bermingham describes the taut valve in a manner that suggests similarities with Applied's claimed inventions. (See, e.g., Bermingham, ¶ 28 (suggesting, without providing any detail, that this valve was configured differently and used for a purpose other than described in the notebook). This is not corroborated and Bermingham later admitted that this valve was just a taut valve considered to replace the taut valve of the Intromit. (Day 1 Tr., pp. 106:13-24, 108:4-109:7.) In any event, even as recast by Bermingham, this valve would not be the claimed inventions of the Applied Patents.

194. The basic concept of valves based on foams was known in the art. For example, the Golub '133 patent described valves on the proximal end of a wound retractor made of foam to seal about a hand or instrument inserted through the foam and that would return to their original shape once the object is removed. (Ex. 745 at col. 4, lines 55-65.) The Beane '577 patent also describes the use of foams for sealing against objects inserted through a wound retractor. (Ex. 762 at col. 11, lines 61 to col. 12, line 1.)

195. As explained further, infra, the inventions claimed in the Applied Patents are all substantially different from the foam-based designs relied upon by Gaya, and any communication by Gaya to Applied of such designs could not have contributed to the inventions claimed in the Applied Patents. Three of the Applied Patents – the '221 patent, the '765 patent, and the '234 patent – require a gel material that forms a zero seal and an instrument seal. (Exs. 8, 40, 667.) The Gaya foam designs are not made of a gel material. They also either require a separate taut valve to provide a zero seal, or act as an interior taut valve that cannot provide an instrument seal. (Sheehan, ¶ 136.) The remaining two Applied Patents – the '755 patent and the '581 patent – require monolithic flanged devices that are adapted to be disposed within an incision. (Exs. 1, 729.) None of the Gaya foam valves are monolithic or capable of being disposed within an incision. (Sheehan, ¶ 136.)

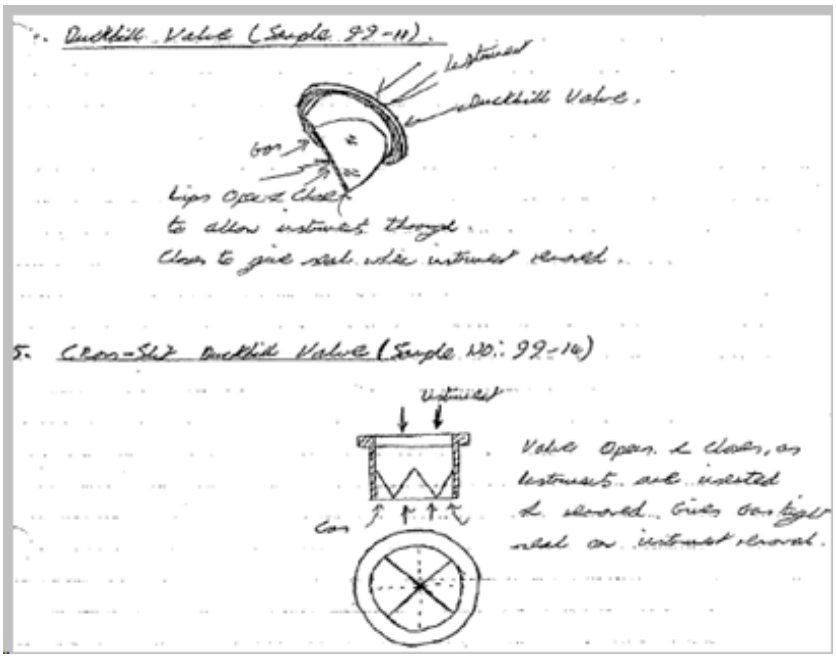
5. Trocar Slit Designs.

196. As evidence of conception of the inventions claimed in the Applied Patents, Gaya also identifies and relies on a variety of trocar "slit designs" found in Gaya notebooks. One example is the sketch reproduced below.



(Ex. 154 at CV11-1406AM0159294-95.) The notebook indicates that a prototype was made and tested. (Id.) The valve did not work as desired, as there was leakage during instrument insertion and removal. (Id.) The notebook entry concluded that further development would be needed.
(Id.)

197. Gaya also relies on trocar duckbill valves reproduced below.



(Id. at CV11-1406AM0159295-97.)

198. Both the slit and duckbill valves were proposed valving methods specific to a Gaya trocar product. (Day 1 Tr., pp. 103:24-104:11; see also Bermingham, ¶¶ 34-37.) The notebooks do not suggest that these were considered for use with hand access devices, and they provide no information as to what types of HALS devices these valves would be used with or how the valves would be incorporated into the HALS devices. (Sheehan, ¶ 141.) Additionally, at least one of the valves had problems receiving instruments larger than 10 millimeters, which is much smaller than a surgeon's hand. (Day 1 Tr., p. 104:20-22.)

199. The general use of duckbill valves in access devices was known in the art, such as described in at least U.S. Patent No. 5,853,395 to Crook ("the Crook

'395 patent") that issued on December 29, 1998, and U.S. Patent No. 5,782,812 to Hart ("the Hart '812 patent") that issued on July 21, 1998. (Ex. 995 (Hart '812 patent) at col. 5, lines 61-65 and Fig. 2; Ex. 756 (Crook '395 patent) at col. 5, lines 30-31.) Figure 2 from the Hart '812 patent, illustrating a cross-slit duckbill valve, is shown below.

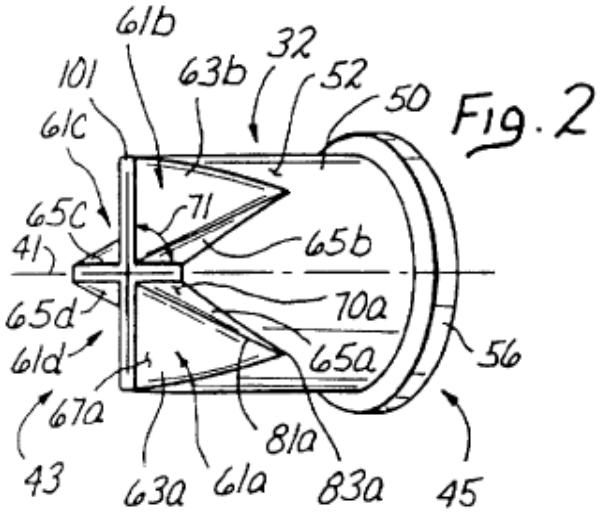


Fig. 2

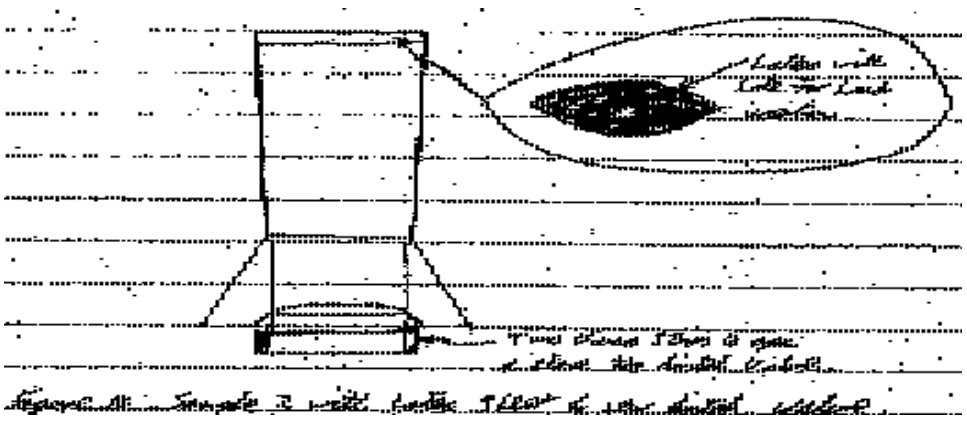
200. Any communication of the general concept of using a duckbill valve by Gaya to Applied would have merely conveyed the state of the prior art.

201. As explained further, infra, the inventions claimed in the Applied Patents are all substantially different from the trocar valve designs relied upon by Gaya, and any communication by Gaya to Applied of such designs could not have contributed anything to the inventions claimed in the Applied Patents. Three of the Applied Patents – the '221 patent, the '765 patent, and the '234 patent – require a gel material that forms a zero seal and an instrument seal. (Exs. 8, 40, 667.) These

slit valves and duckbill valves are not made of gel and are completely different from the claimed inventions. (Sheehan, ¶ 143.) The remaining two Applied Patents – the '755 patent and the '581 patent – require monolithic flanged devices that are adapted to be disposed within an incision. (Exs. 1, 729.) The slit and duckbill valves do not have these features. (Sheehan, ¶ 143.)

6. Latex Valve With Aperture.

202. As evidence of conception of the inventions claimed in the Applied Patents, Gaya also relies on a valve design reproduced below that includes a sheet of latex with a small hole for hand insertion.



(Ex. 154 at CV11-1406AM0159207-08.) As indicated in the figure, the valve would be used in combination with a second, distal valve. (Id.)

203. There is insufficient information provided to reduce this concept to

practice. One would not expect the design to work. Among other problems with the design, one would not expect it to provide an effective instrument seal, especially for instruments of varying size. (Sheehan, ¶ 146.)

204. Additionally, the use of aperture valves in laparoscopic procedures was known by at least March 7, 2000, as demonstrated by at least the Kaji '426 patent. (Ex. 357 at col. 6, lines 23-29 and Figs. 1 and 3.)

205. As explained further, infra, the inventions claimed in the Applied Patents are all substantially different from this aperture latex valve (which is simply a sheet of latex with a hole in it), and any communication by Gaya to Applied of such a design could not have contributed anything to the inventions claimed in the Applied Patents. Three of the Applied Patents–the '221 patent, the '765 patent, and the '234 patent–require a gel material that forms a zero seal and an instrument seal. (Exs. 8, 40, 667.) The aperture latex valve is made of latex, not a gel, and cannot provide both a zero seal and an instrument seal. (Sheehan, ¶ 148.) The remaining two Applied Patents–the '755 patent and the '581 patent–require monolithic flanged devices that are adapted to be disposed within an incision. (Exs. 1, 729.) The aperture latex valve is not monolithic and is not disposed within an incision; rather it is positioned above the incision. (Sheehan, ¶ 148.)

206. Gaya witness Rosney describes the latex sheet with an opening in a manner that suggests similarities with Applied's claimed inventions. (See, e.g.,

Rosney, ¶ 53; Ex. 154 at CV11-1406AM0159207-08 (describing diaphragm sealing against a surgeon's wrist and sealing when the hand is removed).) This is not corroborated and, in any event, would not be the claimed inventions of the Applied Patents. Further, a diaphragm with a permanent hole would leak excessively, and thus never work as a zero seal. (Johnson, ¶ 33.)

7. Designs From Christy Cummins' Notebook.

207. Gaya also relies on a number of sketches found in Cummins' personal notebook.

208. Cummins left Gaya in October 1999. (Cummins, ¶ 11.) He took his personal notebook with him when he left. (Day 1 Tr., p. 181:16-18.) Further, Cummins never showed his notebook to anyone from Applied, met anyone from Applied, spoke with anyone from Applied, or had any other form of communication with anyone from Applied. (Day 1 Tr., pp. 174:19-175:2, 181:19-21.)

209. Gaya does not contend that Cummins' personal notebook was ever shown to Applied. There is no testimony that any sketches from Cummins' notebook were specifically discussed with Applied. Neither the concepts in Cummins' notebook, nor anything else relied upon by Gaya, was shown to or discussed with Applied at the meeting between Applied and Gaya in March 2000. (Johnson, ¶ 30-31; Taylor, ¶ 23-24.)

210. Further, if Cummins had an idea or concept in his personal notebook that he wished to pursue further in his work for Gaya, he would have documented it in a Gaya notebook. (Day 1 Tr., p. 181:10-15.) Cummins also expected others at Gaya to document in the Gaya notebooks ideas of significant importance that Cummins shared with them from his personal notebooks. (Id., pp. 200:25-201:15.) That none of the sketches from Cummin's personal notebook relied on by Gaya appear in the Gaya notebooks is an indication that the sketches were not considered ideas of significant importance and were never developed by Gaya.

211. There is no link in the evidence between Cummins' work and Applied. Because the designs relied upon by Gaya depicted in Cummins' notebooks were not disclosed to Applied, those designs cannot evidence any contribution by Gaya personnel to the inventions claimed in the Applied Patents. This is sufficient to disregard Cummins' work without considering the technical shortcomings in his sketches. (See Applied Proposed FF, ¶¶ 198-206, discussing such shortcomings.) He was not a source of contribution. This is significant because many of the drawing which Gaya relies upon come from Cummins. (See Sheehan, ¶¶ 175, 187, 203, 317, 318, 326, 333, 347, 363, 384, 386, 396, 401-03, 409; Collins, Appendix A, p. 13; Appendix B, p. 11; Appendix D, passim; Appendix E, passim.)

F. Additional Differences Between The Designs Relied Upon By Gaya And The Inventions Claimed In The Applied Patents.

212. Collins offered testimony concerning the role of Bermingham, Caldwell, and Cummins, and Rosney in support of Gaya's contention that they have made contributions to Applied's Patents. (Collins, ¶¶ 31-265.) He also offered a series of detailed Appendices tying the claims in the Applied Patents to Gaya personnel's asserted contributions.

213. The Court finds two overarching flaws in Collins' work that cause the Court to reject his analysis.

214. First, for any given claim of the Applied Patents, Collins relies on multiple designs pieced together in an attempt to demonstrate a conception of the claimed invention. Specifically, he relies upon at least sixteen different designs to arrive at his conclusion that Gaya personnel conceived of the inventions claimed in the Applied Patents. (See Collins, Appendices A-E.) He does not explain how various disparate designs and sketches would be combine and also gives no reason for various combinations to be made. More fundamental the Court's assessment of the flaw, it was Collins himself who combined the different designs. (Day 2 Tr., p. 59:10-19.) He does not rely on any suggestion in the Gaya notebooks or from Gaya personnel to motivate the combinations. (Id.)

215. Collins' own description of the controlling legal standards underscores this flaw. He describes conception in the following terms:

> "Conception," for purposes of inventorship, is the formation in the mind of the inventor of a definite and permanent idea of the complete and operative invention . . . . I further understand that conception is complete only when the idea is clearly defined in the inventor's mind such that only ordinary skill would be necessary to reduce the invention to practice . . . ."

(Collins, ¶ 20; emphasis supplied.) The combinations that Collins advances were formed in his mind–not the asserted inventors' minds. (Day 2 Tr., pp. 59:10-19, 61:7-10.)

216. Second, Gaya also did not address what was known in the prior art. In his trial declaration, Collins never compared the various Gaya design concepts upon which he relies to what was already known in the prior art. (Day 2 Tr., pp. 31:11-14, 32:6-13, 60:8-11.) Likewise, in their trial declarations, Bermingham, Caldwell, Cummins, and Rosney do not compare their design work to what was already known in the prior art.

217. Without evidence that Gaya's personnel conceived the various combinations upon which Collins' analysis is based and without consideration of

the prior art, Collins does not present a credible analysis of what the Gaya personnel actually conceived and potentially contributed. Moreover, without consideration of the prior art, there is no basis to assess whether the information, even if taken at face value, amounts to a cognizable contribution. Applied has demonstrated that virtually all of the design elements upon which Gaya relies were already in the prior art, and without evidence of a combination conceived by the Gaya personnel, there is simply no proof of contribution.

218. Applied offers a claim-by-claim analysis, critiquing Gaya's alleged contributions. While the Court finds that analysis convincing for the most part (see Applied Proposed FF, ¶¶ 211-420), the overarching flaws in Collins' work forestall the need for that detailed analysis. However, by way of illustration, the Court includes a select list of claims where Collins failed to take into account a specific element of the claims in the Applied Patents. (See Appendix.) Those examples are mainly drawn from the work of Applied expert Neil Sheehan ("Sheehan"). The Court found Sheehan's analyses more detailed and more thorough than Collins' work, mainly because he accounted for all the elements in Applied's claim when comparing the claims to Gaya's notebooks and other documentation. For that reason, the Court found Sheehan generally more credible.

219. There are a number of less sweeping flaws that also cause the Court to discount Collins' opinions. First, Collins' assessment of Gaya's disclosures is contrary to the Court's finding that no disclosure of Gaya's new technology was

made prior to Applied's conception. (See Collins, ¶¶ 62-81.) Second, in criticizing the available corroborative documentation for the work of the Applied inventors, Collins failed to take into account the prototypes for the August 31, 2000 animal lab or any of the earlier molds or prototypes. (Day 2 Tr., pp. 67:4-68:12.) Until the Sunday before trial, he had only looked at paper documentation. (Id., pp. 67:11-68:5.) Yet nothing could be more corroborative of the conception of an inventor's ideas than a working prototype embodying his ideas.

G. Miscellaneous.

220. Any Finding of Fact more appropriately characterized in whole or in part as a Conclusion of Law shall be deemed a Conclusion of Law to that extent.

CONCLUSIONS OF LAW

A. Jurisdiction and Venue.

1. The Court has subject matter jurisdiction over Gaya's claims pursuant to 28 U.S.C. §§ 1331 and 1338(a), and 35 U.S.C. §§ 116 and 256.

2. The Court has personal jurisdiction over the parties, and venue is proper in this Court under 28 U.S.C. §§ 1391(b) and (c) and 1400(b) because Applied is a resident in this district.

B. The Law Of Inventorship.

3. The Applied Patents are presumed valid by statute. 35 U.S.C. § 282(a). Similarly, "[p]atent issuance creates a presumption that the named inventors are the true and only inventors." Ethicon, Inc. v. U.S. Surgical Corp., 135 F.3d 1456, 1460 (Fed. Cir. 1998). "The presumption is one of law, not fact and does not constitute 'evidence' to be weighed against the challenger's evidence." Chiron Corp. v. Genentech, Inc., 363 F.3d 1247, 1258-59 (Fed. Cir. 2004) (quoting Avia Grp. Int'l Inc. v. L.A. Gear Cal., Inc., 853 F.2d 1557, 1562 (Fed. Cir. 1988)).

4. 35 U.S.C. § 116 provides that subject matter can be invented jointly by multiple individuals. In such circumstances, all of the individuals who contributed to conception are inventors. Trovan, Ltd. v. Sokymat SA, 299 F.3d 1292, 13001-02 (Fed. Cir. 2002).

5. Gaya bears the burden of proving invalidity or incorrect inventorship by clear and convincing evidence. Microsoft Corp. v. i4i Ltd. Partnership, 131 S. Ct. 2238, 2242 (2011); Ethicon, 135 F.3d at 1461.

6. In the event inventorship is incorrect, 35 U.S.C. § 256 "provides a cause of action to interested parties to have the inventorship of a patent changed to reflect the true inventors of the subject matter claimed in the patent." Fina Oil & Chem. Co. v. Ewen, 123 F.3d 1466, 1471 (Fed. Cir. 1997).

7. To prove that Gaya personnel should be named as the sole inventors on a particular Applied Patent, Gaya must prove that Gaya personnel conceived the complete invention and that none of the currently named Applied inventors contributed to the conception of any invention claimed in the patent. See, e.g., Ohio Willow Wood Co. v. Alps South, LLC, 735 F.3d 1333, 1350 (Fed. Cir. 2013) (sole inventorship requires clear and convincing evidence that not only had the alleged inventor conceived of the invention but also the named inventor had not conceived of any aspect of the invention); Fina Oil, 123 F.3d at 1473.

8. Conception is the formation of a definite and permanent idea of the complete and operative claimed invention in the mind of the inventor. Burroughs Wellcome Co. v. Barr Labs., Inc., 40 F.3d 1223, 1228 (Fed. Cir. 1994); see also Fina Oil, 123 F.3d at 1473. Conception requires that the idea be sufficiently formulated so that only ordinary skill would be necessary to reduce the claimed invention to practice without extensive research or experimentation. Burroughs Wellcome, 40 F.3d at 1228; see also Gambro Lundia AB v. Baxter Healthcare Corp., 110 F.3d 1573, 1577 (Fed. Cir. 1997).

9. Further, conception must be shown by a single idea. It cannot be established after the fact by piecing together different and distinct concepts. See Brand v. Miller, 487 F.3d 862, 870 (Fed. Cir. 2007) (citation omitted) (holding that junior party failed to prove derivation by senior party because it "did not show the relationship between" components and that the record was "[l]acking an explanation . . . as to how the [components] would be arranged to perform the claimed

method"); Singh v. Brake, 317 F.3d 1334, 1342 (Fed. Cir. 2003) (junior party in an interference proceeding failed to established an earlier priority date where "nothing . . . corroborates his testimony that [separate notebook] entries were meant to be read together.").

10. Conception requires the "complete performance of the mental part of the inventive act." Gunter v. Stream, 573 F.2d 77, 80 (C.C.P.A. 1978) (internal quotation marks omitted); see also Dawson v. Dawson, 710 F.3d 1347, 1356 (Fed. Cir. 2013) ("[c]onception requires that the inventor know how his definite and permanent idea of the complete and operative invention is hereafter to be applied in practice.") (internal quotation marks omitted).

11. In order to determine whether any Gaya personnel are inventors, the Court begins with a construction of the claims at issue to determine the subject matter encompassed by such claims. See Trovan, 299 F.3d at 1302. All claims of all Applied Patents are at issue in Gaya's sole inventorship claim. The Court next compares the alleged contribution of the Gaya personnel to the construed claims to determine whether the Gaya personnel have established they are in fact inventors. (Id.)

12. To prove that any Gaya personnel qualifies as a co-inventor on the Applied Patents, Gaya must prove that the Gaya personnel made a significant contribution to the conception of at least one or more claims of the Applied Patents. See, e.g., Shum v. Intel Corp., 633 F.3d 1067, 1083 (Fed. Cir. 2010); Pannu v.

Iolab Corp., 155 F.3d 1344, 1351 (Fed. Cir. 1998).

13. Individuals can be joint inventors even though they did not themselves conceive of the entire invention. Fina Oil, 123 F.3d at 1473 ("One need not alone conceive of the entire invention, for this would obviate the concept of joint invention."); Rhone-Poulenc Agro, S.A. v. Monsanto Co., 445 F. Supp. 2d 531, 549 (M.D.N.C. 2006) ("neither the statute nor the cases relating to joint inventorship requires the simultaneous presence or awareness of all who have contributed significantly toward conception when the last piece of the conception puzzle slips into place.").

14. The alleged inventor must do "more than simply provid[e] well-known principles or explain[] the state of the art." Pannu, 155 F.3d at 1351. "A contribution of information in the prior art cannot give rise to joint inventorship because it is not a contribution to conception." Eli Lilly & Co. v. Aradigm Corp., 376 F.3d 1352, 1362 (Fed. Cir. 2004); see also Nartron Corp. v. Schukra U.S.A. Inc., 558 F.3d 1352, 1358 (Fed. Cir. 2009); Caterpillar Inc. v. Sturman Indus., Inc., 387 F.3d 1358, 1377 (Fed. Cir. 2004); Hess v. Advanced Cardiovascular Sys., Inc., 106 F.3d 976, 981 (Fed. Cir. 1997). Simply assisting the actual inventors to create a commercial device that embodies an already completely conceived invention by suggesting the use of known, off-the-shelf material is also the application of routine, ordinary skill and is not a significant contribution to conception. Ethicon, 135 F.3d at 1460.

15. Whether a contribution to the conception of a claimed invention is significant is measured against the scope of the full claimed invention. Pannu, 155 F.3d at 1351.

16. "[O]ne who merely suggests an idea of a result to be accomplished, rather than means of accomplishing it, is not a joint inventor." Nartron Corp., 558 F.3d at 1359 (internal citations omitted) (alleged contributor is not a co-inventor by posing a result to the inventor and then leaving it to the inventor how to accomplish it); Netscape Commc'ns Corp. v. ValueClick, Inc., 684 F. Supp. 2d 699, 721 (E.D. Va. 2010).

17. Joint inventorship under 35 U.S.C. § 116 requires "some element of joint behavior." Kimberly-Clark Corp. v. Procter & Gamble Distrib. Co., Inc., 973 F.2d 911, 917 (Fed. Cir. 1992). That joint behavior may be minimal. "People may be joint inventors even though they do not physically work on the invention together or at the same time." Burroughs Wellcome, 40 F.3d at 1227; see also 35 U.S.C. § 116.

18. To prove that any Gaya personnel should be named as an inventor on the Applied Patents, Gaya must prove not only that Gaya personnel participated in the conception of the claimed inventions but that conception was communicated to Applied. See Kimberly-Clark, 973 F.2d at 916. For example, joint inventorship requires joint behavior between the purported inventors, such as collaboration or working under common direction. (Id. at 917.) Joint inventorship "can only arise

when collaboration or concerted effort occurs—that is, when the inventors have some open line of communication during or in temporal proximity to their inventive efforts. . . ." Eli Lilly, 376 F.3d at 1359. Further, "each inventor must contribute to the joint arrival at a definite and permanent idea of the invention as it will be used in practice." Fina Oil, 123 F.3d at 1473 (internal quotation marks and internal citation omitted).

19. Alleged co-inventors must establish their co-inventorship by facts supported by clear and convincing evidence. Ethicon, 135 F.3d at 1461.

20. Gaya must also provide corroboration to support its inventorship claims. Conception is required to be corroborated with independent evidence. See Eli Lilly, 376 F.3d at1363-64; Rothschild v. Cree, Inc., 711 F. Supp. 2d 173, 203-08 (D. Mass. 2010).

21. "Corroborating evidence may take many forms. Reliable evidence of corroboration preferably comes in the form of records made contemporaneously with the inventive process." Linear Tech. Corp. v. Impala Linear Corp., 379 F.3d 1311, 1327 (Fed. Cir. 2004); see, e.g., Ethicon, Inc. v. U.S. Surgical Corp., 937 F. Supp. 1015, 1034-35 (D. Conn. 1996), aff'd, 135 F.3d 1456 (Fed. Cir. 1998). Whether the co-inventors' testimony has been sufficiently corroborated is evaluated under a "rule of reason analysis," which requires that an "evaluation of all pertinent evidence must be made so that a sound determination of the credibility of the inventor's story may be reached." Gemstar-TV Guide Int'l, Inc. v. Int'l Trade

Comm'n, 383 F.3d 1352, 1382 (Fed. Cir. 2004) (internal quotation marks partially omitted); Price v. Symsek, 988 F.2d 1187, 1195 (Fed. Cir. 1995).

22. "To meet the burden of clear and convincing evidence, the alleged co-inventors must prove their contribution to the conception of the invention with more than their own testimony concerning the relevant facts." Gemstar, 383 F.3d at 1382. Testimony of Gaya personnel about their alleged conception of the inventions claimed in the Applied Patents "standing alone, cannot rise to the level of clear and convincing evidence . . . ." Symantec Corp. v. Computer Assocs. Int'l Inc., 522 F.3d 1279, 1295 (Fed. Cir. 2008). Instead, the Gaya personnel must supply evidence to corroborate their testimony regarding their purported conception of the claimed invention. The Barbed Wire Patent, 143 U.S. 275, 284-85 (1892).

23. An alleged inventor or co-inventor must corroborate not only his conception but also his communication of such conception to the named inventors. See Price, 988 F.2d at 1196.

24. A determination that no Gaya personnel are inventors of the Applied Patents bars Gaya for lack of standing from pursuing any further determination under 35 U.S.C. § 256 as to whether the named Applied inventors are misjoined. Larson v. Correct Craft, Inc., 569 F.3d 1319, 1326-27 (Fed. Cir. 2009) (plaintiff lacked standing to pursue a section 256 claim without a financial interest in the patents). Federal Circuit law "teaches that a plaintiff seeking correction of inventorship under § 256 can pursue that claim in federal court only if the

requirements for constitutional standing—namely injury, causation, and redressability—are satisfied." (Id. at 1326.) Gaya's interests are unaffected by which particular Applied inventors are named as inventors. Contrast Chou v. University of Chicago, 254 F.3d 1347, 1359 (Fed. Cir. 2001) (exclusion of unnamed inventor affected her entitlement to payment under university's policies).[7]

25. The issue of invalidity of the Applied Patents is not before the Court. However, to the extent Gaya may contend that the Applied Patents are invalid because less than all of the inventors are named–i.e., the Gaya personnel–the Court has resolved that issue in favor of Applied. Gemstar, 383 F.3d at 1381-83.

C. No Gaya Personnel Are Inventors Of Any Claim Of The Applied Patents.

26. The Applied Patents list Ewers, Brustad, Pingleton, Hilal, Dulak, Adlparvar, and Bowes as inventors. That listing of inventors is presumed to be correct. Ethicon, 135 F.3d at 1460.

27. Ewers, Brustad, Pingleton, Hilal, Dulak, Adlparvar, and Bowes working

[7]Similar to cases where the plaintiff's standing is dependent on a determination of patent ownership under state law, but had failed to obtain such a determination, the Court has determined that the Gaya personnel are not sole or joint inventors. See Larson, 569 F.3d at 1327; Jim Arnold Corp. v. Hydrotech Sys., Inc., 109 F.3d 1567, 1571-72 (Fed. Cir. 1997). They, as well as Gaya, have no interest for Article III purposes.

together as a team conceived the claimed invention of the Applied Patents independent of anything Gaya even alleges to have provided. Their conception is corroborated by documentary evidence, including drawings, photographs, and prototypes. Sandt Tech., Ltd. v. Resco Metal & Plastics Corp., 264 F.3d 1344, 1350–51 (Fed. Cir. 2001) ("Documentary or physical evidence that is made contemporaneously with the inventive process provides the most reliable proof that the inventor's testimony has been corroborated.") (emphasis supplied); Woodland Trust v. Flowertree Nursery, Inc., 148 F.3d 1368, 1373 (Fed. Cir. 1998) (corroborating evidence includes "a written document such as notes, letters, invoices, notebooks, or a sketch or drawing or photograph showing the device, a model, or some other contemporaneous record") (emphasis supplied)). Circumstantial evidence of an independent nature may also corroborate, Trovan, 299 F.3d at 1303. "[T]here is no final single formula that must be followed in proving corroboration." Berry v. Webb, 412 F.2d 261, 266 (C.C.P.A. 1969). Here there are multiple modes of corroboration.

28. Gaya has not established any of the required elements of its claims. Gaya has not shown by clear and convincing evidence that it conceived the invention of any claim of the Applied Patents. Gaya has not shown by clear and convincing evidence that it communicated any conception of any claim of the Applied Patents to the Applied inventors. Gaya has not shown by clear and convincing evidence that it conceived any significant contribution to the conception of any claim of the Applied Patents nor that it communicated any such significant contribution to the Applied inventors.

1. Gaya Personnel Are Not The Sole Inventors Of The Applied Patents.

29. Gaya has not established the communication of any HALS design concepts to the Applied inventors until after the Applied inventors had made their inventions. No communications were made during Taylor and Johnson's March 2000 visit to Gaya. The only communications of designs supported by the evidence were designs reflected in documents and materials Taylor received from Bermingham on August 22 and 28, 2000. (See Exs. 197, 337, 886.) By then, Applied's inventions had already been conceived Applied. One cannot claim conception for inventorship purposes on the basis of communications after the inventor has conceived his idea. Additionally, for the reasons described, supra, the documents and materials Taylor received from Bermingham on August 28, 2000 are not evidence that Gaya conceived of the inventions in the Applied Patents.

30. Gaya has failed to establish that the various other concepts it relies on were ever communicated to the named inventors on the Applied Patents, including the designs Gaya relies on from Gaya's lab notebook LN-001 (Ex. 154), Gaya's lab notebook LN-002 (Ex. 156), Cummins' personal notebook (Ex. 242), and the various alleged discussions with Taylor and Johnson in March 2000.

31. Gaya relies upon uncorroborated and conflicting witness testimony to prove communication of these designs. This is insufficient to meet its burden, and for this reason none of the Gaya personnel do not qualify as inventors of the

inventions claimed in the Applied Patents. See Symantec, 522 F.3d at 1296.

2. Gaya Did Not Establish A Conception Of Any Claim Of The Applied Patents.

32. Apart from the issue of communication of any conception, Gaya's various drawings and sketches do not evidence a conception of the claimed invention for any claim of the Applied Patents.

33. None of the designs relied on by Gaya establish that Gaya personnel conceived of the inventions claimed in the Applied Patents. Gaya's reliance on multiple designs pieced together in an attempt to demonstrate a conception of the claims in the Applied Patents is insufficient. See Brand, 487 F.3d at 870; Singh, 317 F.3d at 1342. Further, Gaya's attempt to recast various designs from Gaya's documents beyond the description provided in those documents is uncorroborated and unreliable. See Gemstar, 383 F.3d at 1382-83.

34. Additionally, Gaya's reliance on comparisons of its sketches to drawings in Applied's provisional patent application or in the Applied Patents does not amount to clear and convincing evidence of a relevant conception by Gaya. Whether an individual should be included among the inventors listed on the Applied Patents is determined by whether the person conceived of or contributed to the conception of the inventions claimed in the patents. See, e.g., Fina Oil, 123 F.3d at 1473 ("[t]o be a joint inventor, an individual must make a contribution to the

conception of the claimed invention that is not insignificant in quality, when that contribution is measured against the dimension of the full invention.") (emphasis supplied). The drawings in the provisional patent application are irrelevant to this analysis.

a. Gaya Personnel Did Not Conceive Of The Inventions. Claimed In Applied's U.S. Patent No. 7,473,221.

35. Neither Cummins, Bermingham, Rosney, nor Caldwell are inventors of any of the inventions claimed in the '221 patent. The claims of the '221 patent are directed generally toward an access device with a gel-based valve structure and a supporting cap ring or gel support structure adapted to be attached to an incision seal support structure or wound retractor. (Ex. 40.) The valve forms a seal in the absence of an instrument through the valve and with an instrument inserted through the valve. (Id.) The seal with the instrument is formed between the gel and the instrument. (Id.)

36. None of the Gaya designs demonstrate a conception of or contribution to the conception of these claims. For example, none of the Gaya designs include a gel-based valve structure consisting of either an unencapsulated gel material, an ultragel, or an elastomeric oil mixture that is attachable to a wound retractor and

that forms an instrument seal between the gel and the instrument.[8] Nor does Gaya show how its designs, when combined, demonstrate conception of or a contribution to any of these claims.

b. Gaya Personnel Did Not Conceive Of The Inventions Claimed In Applied's U.S. Patent No. 7,481,765.

37. Neither Cummins, Bermingham, Rosney, nor Caldwell are inventors of any of the inventions claimed in the '765 patent. The claims of the '765 patent are directed generally toward an access device having a valve with two layers, one of which is a gel material. (Ex. 8.) The gel layer forms a seal in the absence of an instrument through the valve and also forms a seal with an instrument inserted through the valve. (Id.) The valve can accommodate a range of instrument sizes. (Id.)

38. None of the Gaya designs demonstrate a conception of or contribution to the conception of these claims. For example, none of the Gaya designs include a multi-layered valve with a self-sealing gel material that accommodates a range of instrument sizes. Nor does Gaya show how its designs, when combined, demonstrate conception of or a contribution to any of these claims.

c. Gaya Personnel Did Not Conceive Of The Inventions

[8]For further examples of missing elements for the '221 patent and the remaining patents discussed in this section, see Appendix.

Claimed In Applied's U.S. Patent No. 8,105,234.

39. Neither Cummins, Bermingham, Rosney, nor Caldwell are inventors of any of the inventions claimed in the '234 patent. The claims of the '234 patent are directed generally toward a surgical hand port having a gel seal valve that includes a support ring and a gel pad. (Ex. 667.) The gel pad forms a seal in the absence of an instrument through the gel pad and also forms a seal with an instrument inserted through the gel pad. (Id.) The gel pad can accommodate a range of instrument sizes. (Id.)

40. None of the Gaya designs demonstrate a conception of or contribution to the conception of these claims. For example, none of the Gaya designs includes a gel pad comprising a molded mixture of an elastomer and oil, much less a gel pad having the other properties claimed in the '234 patent. Nor does Gaya show how its designs, when combined, demonstrate conception of or a contribution to any of these claims.

d. Gaya Personnel Did Not Conceive Of The Inventions Claimed In Applied's U.S. Patent No. 8,016,755.

41. Neither Cummins, Bermingham, Rosney, nor Caldwell are inventors of any of the inventions claimed in the '755 patent. The claims of the '755 patent are directed generally toward a surgical access device that includes a flanged and monolithic pad or seal that is inserted into an incision, seals with the abdominal

wall, and has an opening or access channel that can seal with an instrument inserted through the opening or access channel. (Ex. 1.)

42. None of the Gaya designs demonstrate a conception of or contribution to the conception of these claims. For example, none of the Gaya designs include a monolithically formed access pad or access seal having flanges and made from the materials as claimed in the patent. Nor does Gaya show how its designs, when combined, demonstrate conception of or a contribution to any of these claims.

e. Gaya Personnel Did Not Conceive Of The Inventions Claimed In Applied's U.S. Patent No. 8,496,581.

43. Neither Cummins, Bermingham, Rosney, nor Caldwell are inventors of any of the inventions claimed in the '581 patent. The claims of the '581 patent are directed generally toward a surgical access device that includes a non-inflatable, flanged and monolithic access port that can span the thickness of a patient's abdominal wall and that seals against the abdominal wall and with an instrument inserted through the port. (Ex. 729.)

44. None of the Gaya designs demonstrate a conception of or contribution to the conception of these claims. For example, none of the Gaya designs include a non-inflatable, flanged and monolithic access port designed to be positioned within an incision. Nor does Gaya show how its designs, when combined, demonstrate conception of or a contribution to any of these claims.

f. Gaya Personnel Are Not The Joint Inventors Of Any Claim Of The Applied Patents.

45. Apart from the issue of communication of any conception, Gaya's various drawings and sketches do not evidence a conception of the claimed invention for any claim of the Applied Patents or any significant contribution to the conception of the claimed invention as measured against the scope of the full claimed invention. See, e.g., Pannu, 155 F.3d at 1351. Further no communications were made during Taylor and Johnson's March 2000 visit to Gaya. The only communication of designs supported by the evidence were designs reflected in documents and materials Taylor received from Bermingham on August 22 and 28, 2000. (See Exs. 197, 337, 886.) By then, Applied's inventions had already been conceived by the named Applied inventors. Additionally, for the reasons described, supra, the documents and materials Taylor received from Bermingham on August 28, 2000 are not evidence that Gaya contributed to the conception of the inventions in the Applied Patents.

46. Gaya's HALS designs are significantly different from the inventions of the Applied Patents and are not a significant contribution to the conception of the claimed inventions of the Applied Patents as measured against the scope of the full claimed inventions, even as pieced together by Gaya.

47. Gaya's twist valve designs do not evidence conception of or contribution to any of the claims in the Applied Patents. The twist valve designs that Gaya relies

upon, including the twist valve designs Taylor received from Bermingham in August 2000 (see Exs. 197, 886) are not gel seals or monolithic access pads or access seals/ports as required by the claims of the Applied Patents and are significantly different from the claimed inventions. The Applied Patents do not describe or claim twist valves. Witness testimony presented by Gaya describing Gaya's twist valve designs as similar to Applied's claimed inventions is uncorroborated and thus insufficient. See Eli Lilly, 376 F.3d at 1363-64. Any communication of the twist valve designs by Gaya to Applied was not a contribution to the conception of the inventions claimed in the Applied Patents, as the twist valve designs significantly differ from Applied's claimed inventions, and designs similar to Gaya's existed in the prior art.

48. Gaya's wound retractor designs do not evidence conception of or contribution to any of the claims in the Applied Patents. The wound retractor designs are not gel seals as required by the claims of the Applied Patents that refer to a wound retractor or associated structure and are significantly different from the claimed inventions. Any communication of wound retractor designs by Gaya to Applied was not a contribution to the conception of the inventions claimed in the Applied Patents: The proposals sent by Gaya to Applied in late August 2000 pictured a twist valve combined with a commercially available wound retractor and various wound retractors similar to Gaya's designs existed in the prior art.

49. Gaya's liquid-filled bladder designs do not evidence conception of or

contribution to any of the claims in the Applied Patents. The liquid-filled bladder designs shown in a Gaya lab notebook (LN-001) relied upon by Gaya are significantly different from the gel seals claimed in the Applied Patents, which, in various claims, are claimed as being unencapsulated, consisting of an ultragel, being formed of an elastomeric oil mixture, or having multiple layers. Gaya's liquid-filled bladder designs are none of these things. Indeed, the Applied Patents issued despite the existence of prior art disclosing uses of bladders or other casings to form seals. Further, the liquid-filled bladder designs are too incomplete to enable one of ordinary skill to reduce the design to practice. See Burroughs Wellcome, 40 F.3d at 1473.

50. There is insufficient information provided to reduce the sketched liquid-filled bladder designs described in the Gaya lab notebook to practice. In any event, by the time the designs were allegedly communicated to Applied, Applied already had learned about the same concept months earlier in connection with a December 1999 meeting with Dr. Clayman. Upon further consideration, Applied determined that the concept would not work.

51. Any communication of the bladder designs by Gaya to Applied was not a contribution to conception of the inventions claimed in the Applied Patents, as the Gaya designs differ significantly from Applied's claimed inventions and Applied had already learned of the concept in a meeting with Dr. Clayman months earlier than Gaya's alleged communication. See Kimberly-Clark Corp., 973 F.2d at 916.

52. In any event, any alleged communication of Gaya's bladder designs

would be irrelevant in light of the prior art disclosing the use of a bladder or other casing to form a seal.

53. Gaya's foam-based designs do not evidence conception of or contribution to any of the claims in the Applied Patents. The various foam-based designs relied upon by Gaya shown in Gaya's lab notebooks are not gel seals or monolithic access pads or access seals/ports as required by the claims of the Applied Patents, and are significantly different from the named inventions. The foam-based designs were used only as an interior valve. Any communication of these designs by Gaya to Applied was not a contribution to the conception of the inventions claimed in the Applied Patents: The devices significantly differ from those claimed in the Applied Patents, Gaya's foam-based devices failed to seal, and such devices were already disclosed in the prior art.

54. Gaya's trocar designs do not evidence conception of or contribution to any of the claims in the Applied Patents. The various trocar seal designs relied upon by Gaya were not intended to be used in a hand access device. The trocar seal designs are not gel seals or monolithic access pads or access seals/ports as required by the claims of the Applied Patents, and are significantly different from the claimed inventions. Further, the prototype Gaya tested based on the designs in Gaya's notebook failed. Any communications of these designs by Gaya to Applied was not a contribution to the conception of the inventions claimed in the Applied Patents: The designs are significantly different from those claimed in the Applied Patents, Gaya's prototype failed, and duckbill valves were already disclosed in the

prior art.

55. Gaya's latex design does not evidence conception of or contribution to any of the claims in the Applied Patents. The latex design is too incomplete to enable one of ordinary skill to reduce the design to practice. See Burroughs Wellcome, 40 F.3d at 1473. Further, the latex seal design is not a gel seal or a monolithic access pad or access/seal port as required by the claims of the Applied Patents and is significantly different from the claimed inventions. Any communications of this design by Gaya to Applied was not a contribution to the conception of the inventions claimed in the Applied Patents: The design is significantly different from those claimed in the Applied Patents, is insufficiently described, and the use of aperture valves in laparoscopic procedures is disclosed in prior art.

56. The designs depicted in Cummins' notebook also do not evidence conception of or contribution to any of the claims in the Applied Patents. In addition to never having been shown to Applied, the sketches depicted in Cummins' personal notebook are different from the inventions claimed in the Applied Patents. The sketched designs that refer to gel or jello are significantly different from the gel seals claimed in the Applied Patents, which, in various claims, are claimed as being unencapsulated, consisting of an ultragel, being formed of an elastomeric oil mixture, or having multiple layers. The sketches in Cummins' notebook are none of these things. The sketches also do not depict monolithically formed access seals and nor are they made from the materials specified in other claims of the Applied

Patents.

57. Any communication of the designs sketched in Cummins' personal notebook by Gaya to Applied was not a contribution to the conception of the inventions claimed in the Applied Patents.

58. In addition, the features relied upon by Gaya in its various design work, including the features described in the documents Taylor received from Bermingham in August 2000 (see Exs. 197, 886) were known in the art by 2000. Any communication by Gaya to Applied of these designs would have been nothing more than explaining the state of the prior art, and would not have been a significant contribution to the conception of the inventions claimed in the Applied Patents.

59. Many of the design concepts relied upon by Gaya, such as foam-based valves, liquid-filled bladders, and wound retractors to which valves could be detachably coupled, were described in various Gaya Short Term Irish Patent Applications that the Patent Office considered when granting the Applied Patents. The fact that the Patent Office allowed the claims of the Applied Patents over these Gaya applications further shows the unrelated nature of the inventions claimed in the Applied Patents and the Gaya designs, and that the Gaya designs do not evidence any conception of the inventions claimed in the Applied Patents.

60. Gaya's generalized notion that Gaya personnel conceived of any self-

sealing valves and various other related general goals in connection with HALS devices does not reflect, as it must, the inventions as actually claimed in the Applied Patents, is not supported by any evidence, is not corroborated, and is no more than "an idea of a result to be accomplished, rather than means of accomplishing it." See Nartron Corp., 558 F.3d at 1359 (internal quotation marks omitted)..

61. Gaya also identifies nothing demonstrating a conception of the specific materials included in the claims of the many of the Applied Patents. The selection of the particular materials described and claimed in the Applied Patents for forming access devices with the attributes required for those devices to work was inventive and was more than a routine selection of materials. As evidenced by the detailed discussion of the materials in the specification of the Applied Patents, the specific materials described and claimed in the patents are a significant and important feature of the claimed inventions.

62. Further, Gaya has failed to establish any joint work between Gaya personnel and any of the inventors named on the Applied Patents. Thus, even assuming that Gaya's alleged communications with Taylor and Johnson took place, Gaya did not participate in a joint arrival at a definite and permanent idea of the claimed inventions with the named inventors of the Applied Patents. See Fina Oil, 123 F.3d at 1473 (internal quotation marks omitted).

63. For all these reasons, Gaya has not established any significant contribution to the conception of the inventions claimed in the Applied Patents as

measured against the scope of the full claimed invention. No Gaya personnel are inventors of any claim of the Applied Patents.

D. Miscellaneous.

64. The Secrecy Agreement between Gaya and Applied is irrelevant for purposes of determining the proper inventors here. The Secrecy Agreement is relevant only to the issue of potential contractual relief that may or may not be available to Gaya. In addition, the Secrecy Agreement's four-year limitation is inapplicable, and applies only to potential liability (i.e., financial obligations) of the party who received confidential information based on that party's improper use of information disclosed under the agreement. (Ex. 4, ¶ 4.)

65. Any Conclusion of Law more appropriately characterized in whole or in part as a Finding of Fact shall be deemed a Finding of Fact to that extent.

E. Conclusion.

66. Gaya has failed to establish by clear and convincing evidence that any Gaya personnel are sole or joint inventors of any of the Applied Patents. Applied is entitled to Judgment, and shall submit a proposed form of Judgment within seven days.

Dated: July 11, 2014

James V. Selna
United States District Judge

APPENDIX: EXAMPLES OF DEFICIENT COMPARISONS BETWEEN APPLIED'S CLAIMS AND GAYA'S DOCUMENTATION

All of the examples discussed before are drawn from the independent claims. Thus, the shortcomings necessarily affect the claims dependent on each.

1. U.S. Patent No. 7,473,221.

Claim 1.

• The twist valve designs relied on by Gaya do not include the use of a gel material at all. Rather, they include a valve made from materials such as latex. (Ex. 154 at CV11-1406AM0159276-77; see also Sheehan, ¶ 98.)

• The liquid-filled bladder designs from Gaya lab notebook LN-001 relied on by Gaya are described as being fillable with a liquid gel and do not include an unencapsulated gel seal. (Ex. 154 at CV11-1406AM0159289-90; see also Sheehan, ¶ 171.) The liquid gel would also not have direct contact with an instrument. (Sheehan, ¶ 171.)

• The container from Cummins' personal notebook relied on by Gaya that is filled with a "gel/fluid" does not include an unencapsulated gel material. (Ex. 242 at GAYAX0020683; see also Sheehan, ¶ 175.) Rather, it requires that the gel/fluid used be retained by the container. (Sheehan, ¶ 175.)

• Claim 1 also includes a gel support structure that at least partially surrounds and supports the unencapsulated gel material and that is dimensioned and configured for removable coupling to an incision seal support structure. The designs relied on by Gaya do not include this limitation because, among other reasons, they do not include the concept of an unencapsulated gel as claimed. (Id., ¶ 176.) The general concept of a valve that can be removably coupled to a wound retractor also was known in the art by at least the MacLeod '298 patent (Ex. 352) and the Beane '577 patent (Ex. 762). (Id., ¶ 176.)

Claim 6.

• None of the twist valve designs relied on by Gaya includes the use of a gel material at all, much less an ultragel. (Sheehan, ¶ 182.) Rather, they include a valve made from materials such as latex. (See e.g., Ex. 154 at CV11-1406AM0159276.)

Claim 21,

• None of the twist valve designs relied on by Gaya includes the use of a gel material at all. Rather, they include a valve made from materials such as latex. (See, e.g., Ex. 154 at CV11-1406AM0159276-77; see also Sheehan, ¶ 199.)

2. U.S. Patent No. 7,481,765.

Claim 1.

• None of the designs relied on by Gaya include a multi-layer device that uses a gel material in combination with other flexible materials. (Sheehan, ¶ 212.) Further, none of the designs include the use of a gel in a first layer and a flexible material in a second layer as claimed. (Id.)

• The foam-based designs relied upon by Gaya do not include the gel pad of this claim and they also include a separate valve to seal in the absence of an instrument. (See Ex. 154 at CV11-1406AM0159244-45, CV11-1406AM0159247; Ex. 760 at CV11-1406AM0067020; see also Sheehan, ¶ 213.)

• The twist valve designs relied on by Gaya do not include the gel pad of this claim. (See, e.g., Ex. 154 at CV11-1406AM0159276-77; see also Sheehan, ¶ 214.) These twist valves are also not configured to couple to a body wall. (Sheehan, ¶ 214.)

Claim 14.

• None of the designs relied on by Gaya include a valve having a first, outer layer that comprises a gel pad comprising a gel material. (Sheehan, ¶ 235.) For example, the foam-based designs relied upon by Gaya do not include the gel pad of this claim and they also include a separate valve to seal in the absence of an instrument. (See Ex. 154 at CV11-1406AM0159244-45, CV11-1406AM0159247;

Ex. 760 at CV11-1406AM0067020; see also Sheehan, ¶ 235.)

• The twist valve designs relied on by Gaya do not include the gel pad of this claim. (See, e.g., Ex. 154 at CV11-1406AM0159276-77; see also Sheehan, ¶ 236.) These twist valves are also not configured to couple to a body wall. (Sheehan, ¶ 236.)

Claim 21.

• None of the designs relied on by Gaya include a valve having a gel pad comprising an elastomeric gel and a base layer. (Id., ¶ 249.) For example, the foam-based designs relied on by Gaya do not include the gel pad of this claim and they also include a separate valve to seal in the absence of an instrument. (See Ex. 154 at CV11-1406AM0159244-45, CV11-1406AM0159247; Ex. 760 at CV11-1406AM0067020; see also Sheehan, ¶ 249.)

• The twist valve designs relied on by Gaya do not include the gel pad of this claim. (See, e.g., Ex. 154 at CV11-1406AM0159276-77; see also Sheehan, ¶ 250.) These twist valves are also not configured to seal with a body wall. (Sheehan, ¶ 250.)

3. U.S. Patent No. 8,105,234.

Claim 1.

• The twist valve designs relied on by Gaya do not include the use of a gel material at all, and thus necessarily do not constitute a gel seal valve or a gel pad. (See, e.g., Ex. 154 at CV11-1406AM0159276-77; see also Sheehan, ¶ 268.) Rather, they include a valve made from a twisted sheet of material, such as latex. (Sheehan, ¶ 268.)

• The liquid-filled bladder designs from Gaya lab notebook LN-001 relied upon by Gaya, regardless of whether they are filled with a liquid gel, are not a gel seal valve or a gel pad as required by the claim, such as by being a molded mixture of an elastomer and an oil. (See Ex. 154 at CV11-1406AM0159289-90; see also Sheehan, ¶ 269.) The liquid in the bladder also does not form a valve or seal. (Sheehan, ¶ 269.)

Claim 13.

• The twist valve designs relied on by Gaya do not include the use of a gel material at all, much less constitute a gel seal or a gel pad as claimed. (See, e.g., Ex. 154 at CV11-1406AM0159276-77; see also Sheehan, ¶ 289.) Rather, they include a valve made from a twisted sheet of material, such as latex. (See, e.g., Ex. 154 at CV11-1406AM0159276-77; see also Sheehan, ¶ 289.)

• The liquid-filled bladder designs from Gaya lab notebook LN-001 relied on by Gaya, regardless of whether they are filled with a liquid gel, are not a gel seal or a gel pad as required by the claim, such as by comprising a mixture of an

elastomer and an oil. (See Ex. 154 at CV11-1406AM0159289-90; see also Sheehan, ¶ 290.)

4. U.S. Patent No. 8,016,755.

Claim 1.

• The liquid-filled bladder design from Gaya lab notebook LN-001 relied on by Gaya is not an access pad as set forth in Claim 1. It is not described as being formed from the materials set forth in Claim 1. (See Ex. 154 at CV11-1406AM0159289-90; see also Sheehan, ¶ 314.) Further, this design is not formed monolithically and is not adapted to be disposed within an incision or form a seal with the abdominal wall. (Sheehan, ¶ 314). Instead, it attaches to a patient directly over the access incision. (Id.) Additionally, this design lacks an internal flange and an external flange. (Id.) It is illustrated as a cylinder, without flanges, and the description provided in the notebook also refers to the concept as a cylinder. (Id.)

• The sketched container filled with a gel/fluid contained in Cummins' personal notebook also lacks at least a proximal flange and a distal flange. (See Ex. 242 at GAYAX0020683; see also Sheehan, ¶ 318.) The sketched designs are also not monolithic in that they all include at least a casing or bladder. (Sheehan, ¶ 318.)

Claim 9.

• The liquid-filled bladder design from Gaya lab notebook LN-001 relied on by Gaya is not an access seal as set forth in Claim 9. (See Ex. 154 at CV11-1406AM0159289-90; see also Sheehan, ¶ 332.) The design is not formed from an elastomeric material as claimed. (Sheehan, ¶ 332.) Further, the design is not formed monolithically and is not adapted to be disposed within an incision or form a seal with the abdominal wall. (Id.) Instead, it attaches to a patient directly over the access incision. (Id.) Additionally, this design lacks an internal flange and an external flange. (Id.) It is illustrated as a cylinder, without flanges, and the description provided in the notebook also refers to the concept as a cylinder. (Id.)

Claim 17.

• The liquid-filled bladder design from Gaya lab notebook LN-001 relied on by Gaya is not an access seal as set forth in Claim 17. (See Ex. 154 at CV11-1406AM0159289-90; see also Sheehan, ¶ 346.) It is not formed from an elastomeric material as claimed. (Sheehan, ¶ 346.)

5. U.S. Patent No. 8,496,581.

Claim 1.

• The liquid-filled bladder design from Gaya lab notebook LN-001

relied on by Gaya does not include a proximal flange and a distal flange. (See Ex. 154 at CV11-1406AM0159289-90; see also Sheehan, ¶ 360.) The concept is illustrated as a cylinder, without flanges, and the description provided also refers to the concept as a cylinder. (Sheehan, ¶ 360.) Additionally, the proximal surface of this valve does not define a concavity. (Id.) The fluid in the bladder would tend to push against the bladder, creating a convexity on the proximal surface portion. (Id.) The valve further lacks an intermediate portion with an outer surface having a diameter less than the proximal and distal flange diameters. (Id.) In addition to lacking flanges, the sketches of this design show the valve being wider in the intermediate portion. (Id.) Additionally, as a fluid-filled concept, this design is not monolithically formed, and it is not described as being formed of an elastomeric material. (Id.)

- The concepts from Cummins' personal notebook relied upon by Gaya lack a proximal surface portion that defines a concave area. (See Ex. 242 at GAYAX0020683; see also Sheehan, ¶ 363.) The concepts also are not described as being formed of an elastomeric material. (See Ex. 242 at GAYAX0020683; see also Sheehan, ¶ 363.)

Claim 12.

- The liquid-filled bladder design from Gaya lab notebook LN-001 relied on by Gaya does not include a proximal flange and a distal flange. (See Ex. 154 at CV11-1406AM0159289-90; see also Sheehan, ¶ 383.) The concept is

illustrated as a cylinder, without flanges, and the description provided also refers to the concept as a cylinder. (Sheehan, ¶ 383.) Additionally, the proximal surface of this valve does not define a concavity. (Id.) The fluid in the bladder would tend to push against the bladder, creating a convexity on the proximal surface portion. (Id.) The valve further lacks an intermediate portion with an outer surface having a diameter less than the proximal and distal flange diameters. (Id.) In addition to lacking flanges, the sketches of this design show the valve being wider in the intermediate portion. (Id.) Additionally, as a fluid-filled concept, this design is not monolithically formed, and it is not described as being formed of an elastomeric material. (Id.)

- The concepts from Cummins' personal notebook relied upon by Gaya lack a proximal surface portion that defines a concave area. (See Ex. 242 at GAYAX0020683; see also Sheehan, ¶ 384.) Further, these concepts are not described as being formed of an elastomeric material, much less a thermoplastic elastomer. (Sheehan, ¶ 384.) The foam design in the notebook also appears to require inflation in order to work. (Id. ¶ 386.) The designs sketched in the notebook and relied on by Gaya are also not monolithic in that they all include at least a casing or bladder. (Id.) Thus, these concepts are not evidence of any contribution to this limitation by anyone at Gaya. (Id.)

Claim 21.

- The liquid-filled bladder design from Gaya lab notebook LN-001

relied on by Gaya does not include a proximal flange and a distal flange. (See Ex. 154 at CV11-1406AM0159289-90; see also Sheehan, ¶ 400.) The concept is illustrated as a cylinder, without flanges, and the description provided also refers to the concept as a cylinder. (Sheehan, ¶ 400.) Additionally, the proximal surface of this valve does not define a concavity. (Id.) The fluid in the bladder would tend to push against the bladder, creating a convexity on the proximal surface portion. (Id.) The valve further lacks an intermediate portion with an outer surface having a diameter less than the proximal and distal flange diameters. (Id.) In addition to lacking flanges, the sketches of this design show the valve being wider in the intermediate portion. (Id.) Additionally, as a fluid-filled concept, this design is not monolithically formed, and it is not described as being formed of an elastomeric material. (Id.)

- The concepts from Cummins' personal notebook relied upon by Gaya lack a proximal surface portion that defines a concave area. (See Ex. 242 at GAYAX0020683; see also Sheehan, ¶ 401.) Further, these concepts are not described as being formed of an elastomeric material. (Sheehan, ¶ 401.) In addition, the foam design relied on by Gaya from Cummins' personal notebook also appears to require inflation in order to work. (Id., ¶ 403.) The sketched designs are also not monolithic in that they all include at least a casing or bladder. (Id.) Thus, these concepts are not evidence of any contribution to this limitation by anyone at Gaya. (Id.)